

Final Design

Expert Anesthesiology Monitoring System



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March 23, 2007

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TABLE OF CONTENTS

SECTION	PAGE NUMBER
Abstract	5
1 Introduction	5-9
1.1 Background (client and disability)	6-7
1.2 Purpose of the project	7
1.3 Previous work done by others	7-9
1.3.1 Products	7-8
1.3.2 Patent search results	8-9
1.4 Map for the rest of the report	9
2 Project Design	9-74
2.1 Design Alternatives	10-21
2.1.1 Design 1	10-13
2.1.1.1 Objective	10
2.1.1.2 LabVIEW™	10-11
2.1.1.3 Block Diagram	12
2.1.1.4 Vital Signals	12
2.1.1.5 Patients Prior Information	13
2.1.2 Design 2	13-17
2.1.2.1 Objective	13
2.1.2.2 Circuitry and Filtering	13-15
2.1.2.3 LabVIEW™ Front Panel	15-16
2.1.2.4 Testing	16-18
2.1.2.4.1 LabVIEW™ Testing	16
2.1.2.4.2 Circuit Testing	17
2.1.2.5 Integration	18
2.1.3 Design 3	18-21
2.1.3.1 Objective	18-19
2.1.3.2 Subunits	19-21
2.2 Optimal Design	22-74
2.2.1 Objective	23
2.2.2 Subunits	24-74
2.2.2.1 LabVIEW™ Program	24-29
2.2.2.1.1 Front panel	24-26
2.2.2.2.2 Block Diagram	26-29
2.2.2.2 Connectors and their testing	29-35
2.2.2.3 GE Marquette and ADI Blackfin® Processor	35-42
2.2.2.3.1 GE Marquette	35-37
2.2.2.3.1.1 Hardware Connections....	35
2.2.2.3.1.2 Acquiring Data	36
2.2.2.3.1.3 Data Communications	36-37
2.2.2.3.1.4 Data Parsing	37



2.2.2.3.2 Blackfin®	38-42
2.2.2.4 Patient's Prior Information	42-47
2.2.2.5 Material Requirements	48-54
2.2.2.5.1 Case	48-51
2.2.2.5.2 Interface Screen	51-54
2.2.2.6 Key Pad	54-56
2.2.2.7 Cooling Fan	56-57
2.2.2.8 Power Source	57-60
2.2.2.9 Electrical Circuits	60-64
2.2.2.9.1 Low-Pass Filter	60-61
2.2.2.9.2 High-Pass Filter	61-62
2.2.2.9.3 Band-pass Filter	63
2.2.2.9.4 Leakage Current	63-64
2.2.2.10 Real Time Processing	64-65
2.2.2.11 Digital Signal Processing	65-68
2.2.2.11.1 Fixed Point vs. Floating Point systems	65-66
2.2.2.11.2 Programming languages	67-68
2.2.2.12 Testing	68-70
2.2.2.12.1 LabVIEW™ Testing	68
2.2.2.12.2 Circuit Testing	68-69
2.2.2.12.3 Total Testing	69-70
2.2.2.13 Integration	71
2.2.2.14 Safety	71
3 Realistic Constraints	71-74
4 Safety Issues	74-75
5 Impact of Engineering Solutions	75-76
6 Life-Long Learning	77
7 Budget and Timeline	78-82
7.1 Budget	78-79
7.2 Timeline	80-82
8 Team Members Contributions to the project	82-83
9 Conclusion	83-84
10 References	85-86
11 Acknowledgements	86
12 Appendix	87-88
12.1 Updated Specifications	87
12.2 Purchase Requisitions and FAX quotes	88



Figures:

Figure	PAGE NUMBER
Figure 1: Example front panel of the anesthesia monitoring system.	11
Figure 2: The circuit schematic and Bode Plot of a low-pass filter.	14
Figure 3: The circuit schematic and Bode Plot of a high-pass filter.	14
Figure 4: Example front panel of the anesthesia monitoring system.	16
Figure 5: function generator and oscilloscope setup	17
Figure 6: Optimal Design flow chart.	22
Figure 7: Example front panel of the anesthesia monitoring system	25
Figure 8: BIS TM Vista monitor	26
Figure 9: Example of a well designed block diagram	28
Figure 10: Female port for BIS TM Monitoring system.	30
Figure 11: 9-pin D connector.	30
Figure 12: 25-pin D connector.	31
Figure 13: Physical characteristics of the port.	31
Figure 14: Code to alarm	32
Figure 15: Code for alarm heightening.	32
Figure 16: Code for Noise.	32
Figure 17: Code for error messages.	33
Figure 18: Code to find version number and updates of software.	33
Figure 19: Code to activate recording of events.	33
Figure 20: Block Diagram explaining outline of the parameter update packet	36
Figure 21: Code for a data array.	37
Figure 22: Architecture Core	38
Figure 23: Blackfin [®] insignia.	39
Figure 24: Block Diagram of the Dual-Core	40
Figure 25: EZ-KIT lite from Analog Devices, Inc.	41
Figure 26: Blackfin [®] EZ-extender	42
Figure 27: Age calculator for dosage.	44
Figure 28: Weight calculations using LabVIEW TM	45
Figure 29: Sex calculation using LabVIEW TM	45
Figure 30: Physical condition dosage calculation using LabVIEW TM	46
Figure 31: Example case for the monitor.	49
Figure 32: Front of the case	50
Figure 33: Rear of the case	51
Figure 34: 10.4" LCD monitor	52
Figure 35: Block diagram of LCD display	53
Figure 36: Specifications for the LCD screen	54
Figure 37: Possible button layout	55
Figure 38: Circuit symbol and example of a push-to-make switch	55
Figure 39: Surface mount tactile switch	56
Figure 40: Switch dimensions	56
Figure 41: Cooling fan	57
Figure 42: Double-Fused Three Function Power Entry Module	58
Figure 43: Schematic of Power Supply	58



Figure 44: Specifications for Power Supply	59
Figure 45: Power Cord	59
Figure 46: Power Cord Schematic	60
Figure 47: Power Cord Specification	60
Figure 48: The circuit schematic of a Low-pass filter	61
Figure 49: Low-pass Bode Plot	61
Figure 50: The circuit schematic of a High-pass filter	62
Figure 51: High-pass Bode Plot	62
Figure 52: The circuit schematic of a Band-pass filter	63
Figure 53: Circular buffer operation. This shows an example of how a circular buffer will look at one instant (a) and the following instant (b).	65
Figure 54: Floating and Fixed point trade offs	66
Figure 55: Programming trade-offs.	67
Figure 56: Example Loop code	67
Figure 57: function generator and oscilloscope setup	69
Figure 58: Biopac electrodes	70
Figure 59: Biopac clip leads	70

Table	PAGE NUMBER
Table 1: EEG and ECG filtering parameters.	15
Table 2: Important Code.	33
Table 3: processed EEG Data From EEG snippet code.	34
Table 4: Header information for EEG snippet code.	34
Table 5: processed variables and spectra sent to the host once every second code.	34
Table 6: Raw EEG data code.	34
Table 7: contains BIS history data records code.	35
Table 8: code to indicate an event was marked.	35
Table 9: EEG and ECG filtering parameters	61



Abstract:

This anesthesia monitoring system is a well designed device that will read, interpret and display values by retrieving inputs from the aspect medical BISTM EEG monitor and the GE-Marquette anesthesia monitor. This will be done by using a transducer to pass the data from the two monitors to a Blackfin[®] chip, which will be programmed with a LabVIEWTM. These transducers will have to be able to attach to both the monitors and then alternatively have to connect to the Blackfin[®] chip within the monitor. This information will then be processed and exported to a LCD screen that will display the level of consciousness of the patient, using their prior information, and the two monitors. Then this information will be used to determine a dosage of anesthesia that should be applied to the patient. This project is necessary to create a program that can adequately interpret the level of consciousness of the patient under anesthesia, time stamp the data, and then give the best possible dosage to the anesthesiologist to maintain the proper level amnesia, analgesia and immobility. This device is different from other past devices because it will allow the use of two of the top monitoring systems which will then be analyzed and used cooperatively to give the anesthesiologist a number to use for the administration of anesthesia and the value can then be used to support the anesthesiologist if something goes wrong. All the information will be time stamped and rectified by the program, giving a hard copy of the surgery numerically for scrutiny.

This device is going to have to be using the Blackfin[®] chip to run the LabVIEWTM program and process the information without a computer. This is possible and will be run using only the GE-Marquette anesthesia monitor and the aspect medical BISTM EEG monitor for data input. The information will then be used to calculate the dosage that should be applied and displayed on the LCD screen which will be attached directly to the Blackfin[®] chip using the display outputs.

1 Introduction:

The following proposal is an in depth explanation of how a specialized unit for determining the consciousness level of a patient to help the anesthesiologist maintain vigilance can be designed. Chief of Trauma Anesthesiology at Hartford hospital, Dr. Joseph McIsaac, is the main client and his needs will be considered for all aspects of this design. The principles of engineering will be followed in determining the best cost efficient design encompassing all of the needs of the client. An informative description of the project's goals are outlined which includes the device requirements and its overall abilities. Possible programs and components will be highlighted for use as well.

This device is going to use measurements of 3 signals to determine the level of consciousness of a patient under anesthesia and find if more anesthetic needs to be applied. Mainly the monitor will focus on the data that is received from the GE-Marquette anesthesia monitor, the aspect medical BISTM EEG monitor, and will have to include time stamping. During the process of anesthesia the patient will have data that will be incorporated into the LabVIEWTM program, analyzed and the data in graphical form and then recommend an applied dosage of anesthesia.



The development of new software and hardware has given anesthesiologists hope for additional improvements on the current anesthesiology monitoring systems. LabVIEW™ is the new data acquisition software that will be used in this project to create measurements and a calculated level of consciousness on a clear front panel. This device should be reliable and easily used throughout a surgical endeavor. The settings should be easily managed allowing any level of experience technician to update them. The front panel will display clear graphs with the corresponding numerical values and appropriate labels. The device should be able to withstand a great deal of time in the surgical rooms and be durable enough to withstand everyday use. The device should have a clean and purposeful appearance in the fact that there should not be any wasted space as the device will be in close proximity of patients while maintaining accessibility without compromising the surgery.

The device will then be in such a way which minimizes noise through using analog filtering and amplifications built and after the signal manipulations the data will be sent to the LabVIEW™ program. In the final product the program will be transferred to a Blackfin® chip, which will allow the surgeon to control the functions of the LabVIEW™ program without a personal computer which optimizes the device's functionality in the surgical environment. The components necessary for this device consist of a screen, mother board, microprocessor, and a box to contain the internals. Figure 1 shows a flow chart of the operations of the anesthesia monitoring system.

This design is slightly different then the last because the imported signals will be data received from the GE-Marquette™ anesthesia monitor and the Aspect Medical BIS™ EEG monitor and displaying it on a LabVIEW™ program that will be able to manipulate the received data, time stamp it, and correlate it to a dosage of anesthesia for the patient.

1.1 Background (Client and disability):

Doctor Joseph McIsaac suggested that he was in need of a device that could import information from the GE-Marquette™ anesthesia monitor and the Aspect Medical BIS™ EEG monitor's, time stamp them and then use that information to recommend a dosage of anesthesia to maintain a proper level of consciousness for the patient. Our client is interested in the education of students and the advancement of his ability to become a better anesthesiologist. This project fills is a chance for the client to support students in learning and simultaneously create a safer environment in the operating room for patient and surgeon alike.

As an anesthesiologist is judging the level of consciousness of each individual patient they are using differential equations and precise calculations of fuzzy logic as described by Joseph McIsaac. He explained the procedure as an educated guess and check that has to be monitored and then reconsidered through the full time that the patient is on anesthesiology. The anesthesiologist must also consider each individual patient based on their prior resistance, acute and chronic disease states, age, weight, gender, exercise tolerance, medication usage, habits such as smoking, drug and alcohol use. The doses that are applied take time to affect the patient so as more medicine is added to the patient one must wait till they are sure the "poison" has taken its effects on the consciousness of the patient.



Doctor McIsaac suggested that the BIS monitoring system by GE-Marquette™ anesthesia monitor should be considered as the basis for our project. He supplied the project with a manual and some background information that may help direct the project more efficiently.

1.2 Purpose of the project:

This project's main objective is to develop a device that will act as an "Automatic Anesthesia Expert System". With this device the anesthesiologist should be able to see all of the patient's relevant information, vital signs and their level of consciousness. The main function is to help the anesthesiologist perform with the most information possible about the patient's level of consciousness through examination of the information provided by the GE-Marquette™ anesthesia monitor and the Aspect Medical BIS™ EEG monitor. This information will include the patient's prior information and give a diagnostic evaluation of consciousness and the proper quantity of anesthesia that the patient should receive to be properly sedated. This will all be time stamped to allow for reconstruction of the events in the surgical room during the surgery.

Since new software and hardware has been designed recently it is expected that these new influential materials will help to advance the anesthesiology monitoring systems. LabVIEW™ is the new software that will be used in this project to calculate a level of consciousness on a clear front panel, using the GE-Marquette™ anesthesia monitor and the Aspect Medical BIS™ EEG monitor. This device should be reliable and easily used throughout a surgical endeavor. The settings should be easily changed and the front panel should display clear graphs and needed numerical data with clear labels. The device should be able to withstand a great deal of time in the surgical rooms and be durable enough to withstand every day use. The device should have a clean and purposeful appearance in the fact that there should not be any wasted space, as the device will have to be close to the patient and easily accessed without being in the way of the surgeons.

1.3 Previous Work Done by Others:

1.3.1 Products

Considering that there are previously designed anesthesiology monitoring systems on the medical market already, there must be a reason to use this new design. The client has pointed out that the BIS monitoring system is available and is the model that is being used as an example. The SNAPP II is another anesthesiology monitoring system that is also on the market that has been researched.

The main model that will be examined and used as a guide is the Aspect Medical Systems BIS™ VISTA or GE anesthesia machine the BIS™ monitor. The BIS™ monitor relies on an Electroencephalogram (EEG) to determine the level of consciousness of a patient and then displays a number between 1 and 100 that corresponds to their consciousness. The BIS™ monitor also highlights and acceptable region to which the patient is within the correct level of consciousness for the surgery to continue without amnesia, analgesia, and immobility becoming a factor. There is also an alarm that will sound if the patient leaves the range at which would be considered approaching brain damage or a waking state.



Another model that is available on the market is Everest Biomedical Instruments anesthesia monitoring system called the SNAP II. This device is similar to the BISTM monitor in that it mainly focuses on the level of consciousness of the patient relevant to their electroencephalogram wave and supplies a level of consciousness numerical value between 1 and 100. The SNAP also has alarm limit bars that will show exactly whether the patient is within acceptable range of consciousness or not. There is also an elapsed time clock that shows exactly how long the patient has been under anesthesia. There is also a battery symbol which shows exactly how much longer the device will work before it dies.

1.3.2 Patent Search Results

Thoroughly searching for United States patents is an essential part of beginning a project design. If there are any similar designs that may be infringed upon the design team must know about them and make sure to either find their own method or honor the patent. Intellectual property rights are formed by a patent which gives exclusive rights by the state to a patentee for a certain period of time in exchange for the right to regulate public disclosure of certain details of a device or method or composition of matter, which is new, inventive, and useful for industrial applications.

The first patent was the Vital signs monitoring system patent number 4,705,048 in November 10, 1987. This patent includes the first sensor unit including a microphone for mounting on the patient's chest for picking up breath and heart sounds with a filter and automatic gain control circuit. There was also a second sensor unit which positioned a microphone beneath the blood pressure cuff for picking up the blood flow sounds to determine blood pressure. There were also earphones for monitoring the selected sounds by the physician on hand.

The next patent is a continuation of the first one with a number of 5,010,890 in April 30, 1991. This one has one alteration that allows for continuation of the patent. The patent now includes a switch selector which allows the physician to move freely throughout the operating room while still maintaining the portable receiver that allows the physician to hear the monitoring system.

The next patent consists of an anesthesia machine with a head worn display which includes the gas delivery system control and a patient monitor system in full cooperation. This patent is the anesthesia machine with head worn display which was passed on July 9, 2002. The measured values of the sensor can be displayed on the head worn display device which has stereoscopic capabilities. The monitor includes communication ports for selectively monitoring the sensors of a similar anesthesia machine which can be remotely positioned and the other port can be saved for downloading patients medical records from a hospital medical record computer. This entire system is wireless and can facilitate the anesthesiologists movement throughout the operating room.

The fourth patent that was found is closer to the design that will be used to suit the needs of this monitoring system. This monitor patent is an EEG operative and post-operative patient monitoring method on May 23, 2000 and was designed mainly to focus on the



electroencephalograph (EEG) of the patient involved in the surgery. This patient suggests that by modeling the brain waves, both ongoing and evoked by stimuli, are amplified, digitized and recorded. The brain waves of the patient prior to the surgery are used and compared to the brain waves during the procedure to maintain vigilance over the patient's consciousness. This method focuses mainly on the relative power in the theta band which indicates blood flow, and prolongations of the latency periods under brain stem stimuli as indicated by the patient's ability to feel pain.

The last patent that was found to be relevant was the EEG operative and post-operative patient monitoring system and method passed on December 23, 1997. This method focused on the electroencephalograph (EEG) system monitors patients during and after medical operations to make sure that sufficient anesthetics are being used to attain the desired plan of anesthesia. This device functions by examining the brain waves of a patient and determining if more or less anesthesia is required.

1.4 Map for the rest of the report

For the duration of this final report the design, budget and other engineering considerations will be considered and discussed. Directly following this will be the alternative designs and the optimal design of the expert anesthesiology system. They are however different from the final design and the optimal design due to conflicts between the client, advisor's, and engineers involved in the development of this device. These changes will be discussed as well and the complete final design will be discussed thoroughly. By examining the alternative designs, it becomes evident the direction at which the project went and where things had to be reconsidered. Following these designs will be the realistic constraints, safety issues, and impact of engineering solutions. While the device was being designed the realistic constraints, safety issues and impact of engineering solutions must be considered and well addressed. By considering the impact of engineering solutions, the engineers must consider the possible effects of this device on different areas in society, such as environment, economy and on the rest of the world. After this life-long learning is discussed and was developed through out this designing process. Through out the development of this device, there have been many lessons learned and many hurdles missed. The end of the report contains a timeline for construction of the device, the budget, and the team member's contributions to the report and the design of the device. Then lastly the acknowledgments, references, and the appendix is attached which displays the final specifications.

2 Project Design:

This project has been a process of research and revision that has been changed week by week to obtain the best possible device to meet the needs of the client and advisor. This section displays the different designs that were considered and researched to create the expert anesthesiology monitor. Throughout the alternative designs many changes were made, reasons for the changes and a full explanation of the changes are discussed. The optimal design was chosen to be the most effective to meet the application purposes because it is the only one that truly meets the total requirements of the device which has been changed and re-evaluated in



recent weeks. This design seems to be capable of performing all the functions necessary to meet the requirements of this projects final purpose.

2.1 Design Alternatives:

2.1.1 Design 1:

2.1.1.1 Objective:

The first design for the expert anesthesia monitoring system focused on obtaining vital signals from a patient under anesthesia. The main focus of the design was to make a clear display panel that would give the anesthesiologist an easy view of all the signals at hand. This device was designed to use measurements of a few vital signs to determine the level of consciousness of a patient under anesthesia. Mainly the monitor will focus on the patient's physical condition, medical conditions and prior exposures. During the process of anesthesia the patients ECG, volumetric capnography, blood pressure and their EEG signal would have been taken and used to develop a level of consciousness of a patient.

The device would then be built to specifications that would support the LabVIEW™ program. The program would have been transferred to a data chip, which will allow the chip to control the functions of the LabVIEW™ program without a personal computer. The components necessary for this device consist of a screen, mother board, microprocessor, and a box to contain the internals.

2.1.1.2 LabVIEW™

The front panel for this design has a few preliminary aspects that need to be addressed. The main focus of the front panel is to have a clear graphical and numerical display of the most important data. The graphs will display as close to real time as possible the patients ECG, volumetric capnography, blood pressure and their EEG signal. Each graph will have separate alert levels that will set off the visual and audio alarms to warn the anesthesiologist that the patient is becoming conscious or beginning to fall into an unrecoverable state. These graphs will be colorful in a way that will allow for color segregation between graphs. The numerical values that will be displayed to show the level of consciousness of the patients will be large and clearly displayed next to their corresponding graph. Figure 1 shows a rough estimate of the visual appeal of the front panel.

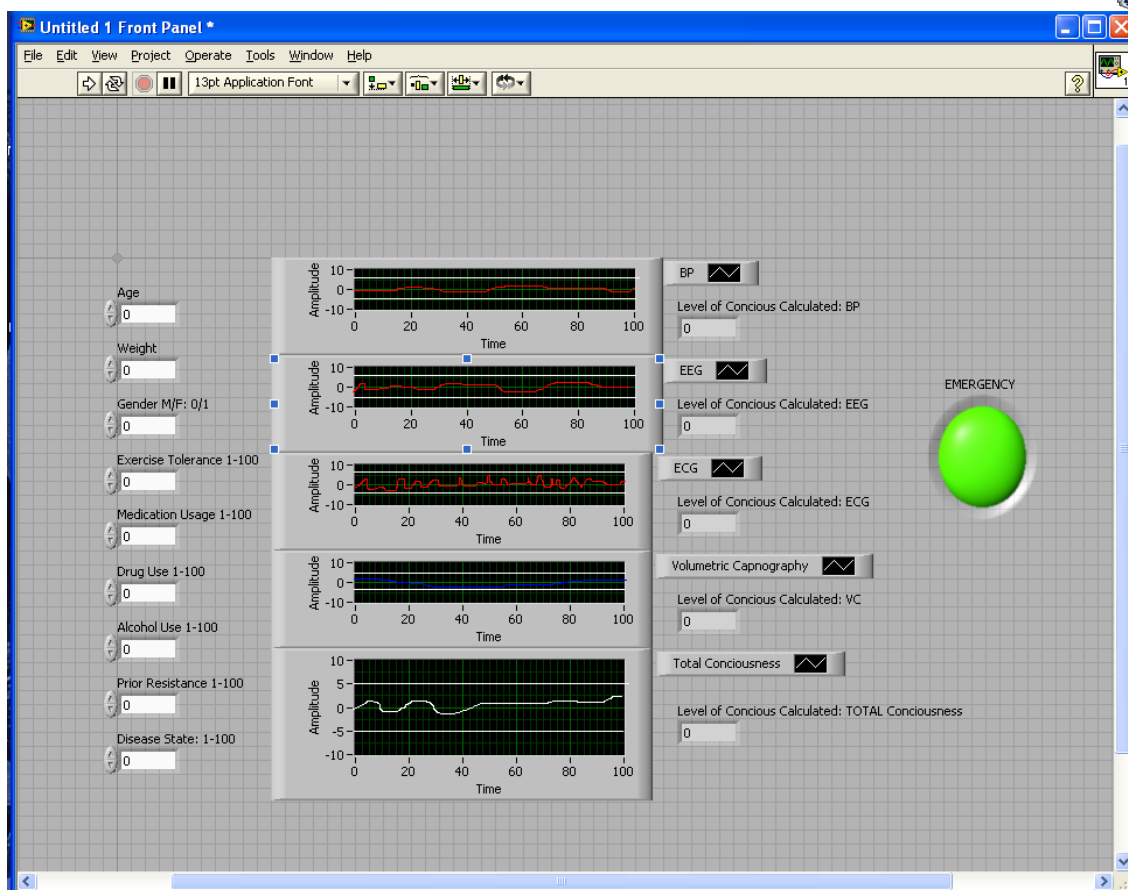


Figure 1: Example front panel of the anesthesia monitoring system.

The patient's information must be easily manipulated on the front panel by the anesthesiologist. These factors consist of the patient preliminary statistics based on their prior resistance, acute and chronic disease states, age, weight, gender, exercise tolerance, medication usage, and habits such as smoking, drug and alcohol use. These will all have to be configured neatly and clearly on the front panel so that the anesthesiologist can alter these during the procedure if necessary. There is a chance that a patient may lie to the doctors and the information given maybe wrong for one reason or another. This is why it is necessary to make the preliminary statistics easily manipulated, and ensure the program is not completely dependent on these factors.

The main model for the front panel is being compared to the Aspect Medical Systems BISTM VISTA or GE anesthesia machine the BIS monitor as displayed in figure 3. The BISTM monitor relies on a clear graph of an Electroencephalogram (EEG) to determine the level of consciousness of a patient at a moments notice by the anesthesiologist and then displays a number between 1 and 100 that corresponds to their consciousness. The BISTM monitor also highlights an acceptable region to which the patient is within the correct level of consciousness for the surgery to continue without amnesia, analgesia, and immobility becoming a factor. There is also an alarm that will sound if the patient exceeds the previously determined range to alert the anesthesiologist of the patient approaching brain damage or a waking state.



2.1.1.3 Block Diagram

The block diagram for the program will be aimed to meet the code followed by national instruments programmers, which consists of common rules to pursuing a proper program. The program should be clear and easily manipulated. The titles of all the different parts of the program are necessary when working with the program and problem shooting. The DAQ must be used in a manner that allows the program to take different inputs and apply them all to one block diagram.

The block diagram is going to have a case structure that will allow for the calculations of each of the vital signs and then the calculation of the level of consciousness produced from them. Each vital sign will have its own portion of the block diagram. The case structures will allow the anesthesiologist to use individual portions of the program and disconnect others if the surgery is interfered with by the sensors.

The block diagram will include global variables that will be placed outside the main loops. This will allow for the numbers to be manipulated at any point in the device's process. Each of these separate loops can be recalled and used in multiple places in the program making the information easy to work with.

An example of a block diagram that fits the requirements that we are looking to pursue is shown as figure four. This diagram is clear, well labeled, and organized in an easily followed manner. This is extremely important in creating a good environment for fixing and accessing problems that may arise during testing or even during later uses. There are flaws that tend to escape the grasp of the testing atmosphere and are only discovered when the device is used in the actually application it was designed for. These errors will have to then be examined and corrected after the device has been cleared for use. This might mean someone unfamiliar with the design may have to navigate the block diagram, find the error, and reprogram the section. If the block diagram is impossible to follow this job becomes immensely more difficult.

2.1.1.4 Vital Signals:

This design focused on four man vital signals to determine the level of consciousness of the patient. The first signal was the ECG which would help to determine the level of consciousness by determining how fast the heart was beating, which in turn would give a parameter from which a comparison could be made from one state to the next. When the heart rate drops the patient is in a more relaxed state and this can be used to judge the level of consciousness. The next signal that was used was the EEG or electroencephalograph. The delta and theta waves are more prevalent when the patient is unconscious and the alpha wave is more prevalent when the patient is awake and fully functional. Then the blood pressure of the patient could be used to determine consciousness as well. The blood pressure automatically drops when the patient is unconscious and the degree of change can be used to determine the level of consciousness of the patient. The last vital sign was volumetric capnography, which would be used to determine the amount of respiratory carbon dioxide leaving the patient. This in turn will help to find how much oxygen the person is using and exactly how conscious they are.



2.1.1.5 Patients Prior Information:

While considering prior resistance, acute and chronic disease states, age, weight, gender, exercise tolerance, medication usage, and habits such as smoking, drug and alcohol use a patient has had prior to the anesthesia the average range for vital signs will be much more readily available. These estimates will increase or decrease the alarm levels of the patient by determining the amount that the person's vital signs will be affected by these prior experiences. For example if the patient is between a certain age range the upper limit will be lowered because the anesthesia drugs will have a stronger effect on them. Some of the personal information used will have a stronger effect than others, such as weight and prior drug use. The main problem with using information given by the patient is that the patient may lie about some information due to a fear of punishment. If a patient has prior experiences with pain killers they may be more likely to need more drugs to keep them at the correct consciousness level but they may not tell the anesthesiologist for fear of persecution. When the anesthesiologist realizes that the drugs are not causing the amount of anesthesia that they are supposed to, it maybe appropriate to change the prior drug usage to a higher level to account for this resistance during the procedure.

2.1.2 Design 2

2.1.2.1 Objective

The primary goal for this design was to improve and expand on the basic outline created in design 1. Like design one, two still included the four vital signals and their corresponding transducers for EEG, ECG, volumetric capnography, and blood pressure. The design, like before, takes the signals obtained from the four transducers and determines the level of consciousness of the patient who's under the anesthesia through the use of the data acquisition software LabVIEW™. The improvements and expansions in this designed were in filtering, the presentation of the data, testing, integration of the system into the final product.

The filtering has been specified to be done completely in the analog domain. This method of using all hardware for filtering and amplifying is commonly used for applications that require a high degree of accuracy. The front panel in the first design was changed from displaying all of the signals to a simpler design. This design explained the method for testing the program and device for design two. The section provides guidelines for testing the program and the circuitry individually and then provides a way to test the device after all of the components have been integrated into one unit. Lastly, integration methodology was investigated, which in design one was neglected.

2.1.2.2 Circuitry and Filtering

Analog filtering and amplification is more effective than digital filtering and amplification because in the analog domain can eliminate noise and amplify the signals with more accuracy. The proposed circuitry that will be used in design two are low-pass and high-pass filters. The purpose of the low-pass filter is to effectively attenuate all of the undesirable high frequency noises. Figure 14 is an example of a second order low-pass filter. The cutoff



frequency is determined with this equation: $f_{OL} = \frac{1}{2\pi R_1 C_1}$. The distinguishing features that make

it second order filter is the second set of resistor/capacitor combination connected to the positive terminal. The low-pass filter is shown in figure 2 through the graphical interpretation of using the bode plot method.

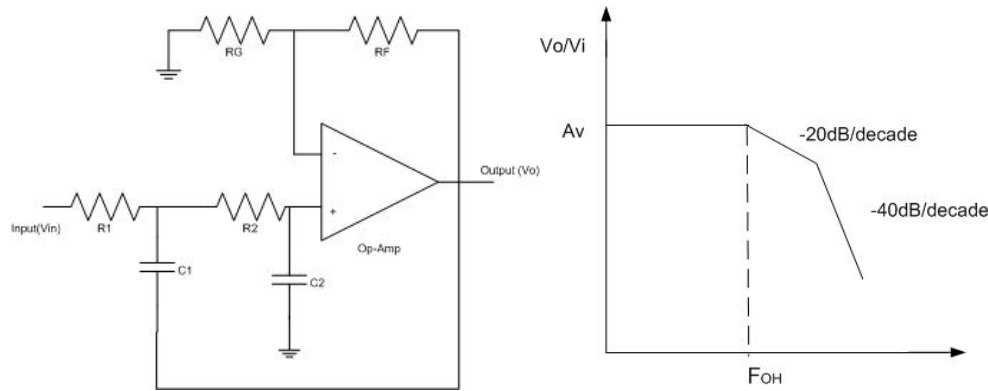


Figure 2: The circuit schematic and Bode Plot of a low-pass filter.

The high-pass filter is created with a similar setup to the low-pass filter. However, the C1, C2 and R1, R2 positions are switched. Opposed to the low-pass filter this setup attenuates low frequencies reducing any noise with a frequency below the cutoff frequency to be eliminated. Figure 16 displays the High-pass filter. The cutoff frequency is determined in the same way as the low-pass. The equation relating the filter with the circuit is $f_{OH} = \frac{1}{2\pi R_1 C_1}$.

The cutoff equations can be used to adjust the filtering parameters to accommodate the individual vital signals for the expert anesthesiology monitoring device. The graphical display of a high-pass filter is shown in figure 3.

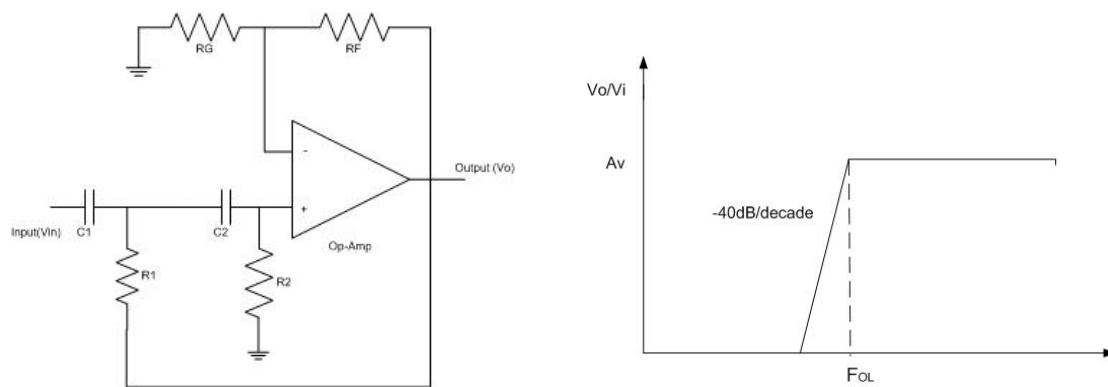


Figure 3: The circuit schematic and Bode Plot of a high-pass filter.

These filters also provide an amplifying effect creating clearer output and will allow for easy analysis. The amplification is influenced by ratio between resistors RG and RF. The



equation relating these resistors is $A_v = 1 + \frac{R_F}{R_G}$. Depending on the type of signal the specific

circuit is dealing a different combination of resistors will be used for applying the correct amplification. Placing these two filters in series provides filtering effects which are called band pass and band stop filter depending on the order which they are placed. A band pass filter is a high and low pass filter, relatively; the band stop filter is in the opposite order which is used for eliminating certain frequencies within the valuable data. The frequencies for which these filters have to be adapted to are displayed in Table 1.

	EEG Signal		ECG Signal	
EEG waves	f_{OH}	f_{OL}	f_{OH}	f_{OL}
Alpha	0.0833Hz	0.125Hz	0.05Hz	40/100/150Hz
Beta	0.0333Hz	0.077Hz		
Delta	0.143Hz	0.25Hz		
Theta				

Table 1: EEG and ECG filtering parameters.

2.1.2.3 LabVIEW™ Front Panel

The front panel like previous designs still displays clear graphical and numerical values, which represent information that the anesthesiologist must be aware of. However this design was developed in a way that would make the front panel simpler by making the four vital signs selectable through the use of a drop down menu. The reasoning behind this idea is, currently anesthesiologists primarily use the EEG to determine the patient's level of consciousness with a high degree of accuracy. Therefore additional vital signals would aid in pin pointing the reason for the patient's fluctuating level of consciousness but are not necessary in determining their level. The default vital signal would be set to the EEG because this is the anesthesiologist primary signal. Below the selectable graph would be the overall level of consciousness display, like in design one, would incorporate all of the transducer signals to produce the values. Figure 4 is the example front panel for design two.

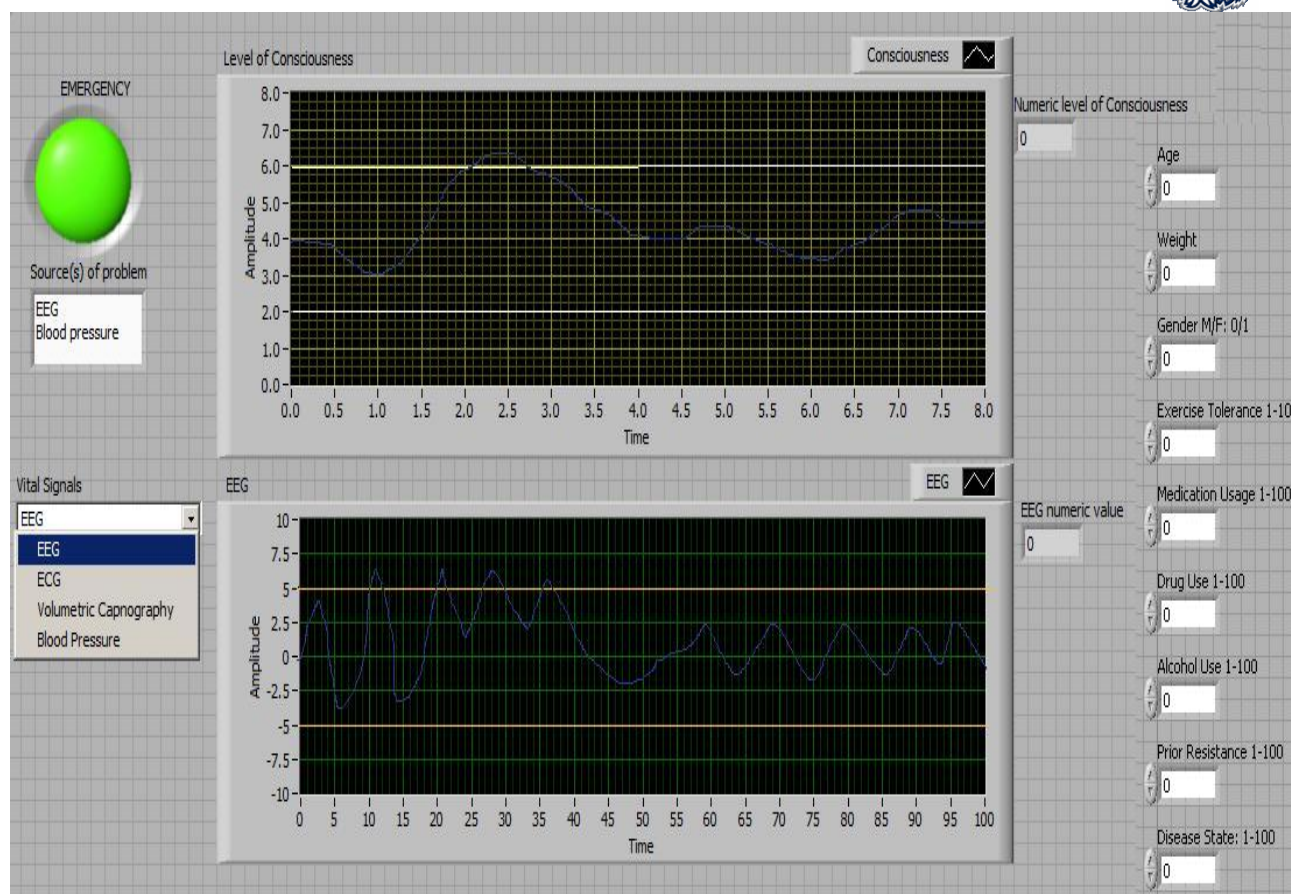


Figure 4: Example front panel of the anesthesia monitoring system.

2.1.2.4 Testing

2.1.2.4.1 LabVIEW™ Testing

The testing of LabVIEW™ will involve a break down of the program into smaller portions to make sure that all the parts work independently before combining them into one program. The program will mostly be broken down into each individual component. After each of the signals are working independently and the errors are deciphered and fixed, the program will be consolidated into and will be run through one Data Acquisition or DAQ assistant. This is where most of the problems in the program should be experienced. When combining multiple working signals into one, there is an error rate that has to be accounted for. The chance that multiple programs can be combined without interference is implausible.

The testing without the circuits attached can be done with programmer installed data. Instead of using the circuits to input the data from the patient, signals can be simulated and applied to the program to make sure that the program can process and display the data correctly without error. At this point the filters can be tweaked and the noise will be separated from the signal and can be filtered out. This will allow for the most precise measurements. Knowing the signal that should be outputted will allow for a proper diagnosis of noise and error in the outputted signal and graph.



2.1.2.4.2 Circuit Testing

Testing the electrical hardware will be done in two ways. First using PSpice the circuit build and simulated with the calculated resistive and capacitive components. Once the board has gone through extensive virtual trouble shooting it will be translated into electronic hardware. This hardware will be required to undergo additional tests to check whether or not there were errors incurred during fabrication and soldering of the components.

Each of the signals will require specialized components to meet their amplification and filtering needs. First the circuitry will be verified by testing the amplification and filtering. Given that each signal requires a unique set of filtering and amplifying parameters the circuitry components will be customized set their requirements.

For example the EEG amplitudes and frequency components vary from 10-100 μ V and from 0.5-30Hz respectively and within these general parameters there are sub parameters correlating to the different periodicity's which compose the EEG signal. Each of these periodicities is characterized by a more specific frequency and amplitude as well as the conditions which they are most apparent. The filtering of this design will be completed solely in analog domain.

The approach to verify the functionality of the circuit will be to connect a function generator to the input of the circuit board and to channel 1 of an oscilloscope and connect channel two of the oscilloscope to the output. This will provide an easy way to compare the inputted signal to the outputted signal. The input signal will be attenuated by the same scale that that output signal is amplified by which will reproduce the un attenuated signal. To manually test the filtering of the circuit board the frequency of the created signal will be move around each cutoff frequency. As the frequency exceeds a cutoff frequency the signals should be attenuated to about zero. Figure 5 displays a general setup for a function generator and oscilloscope.

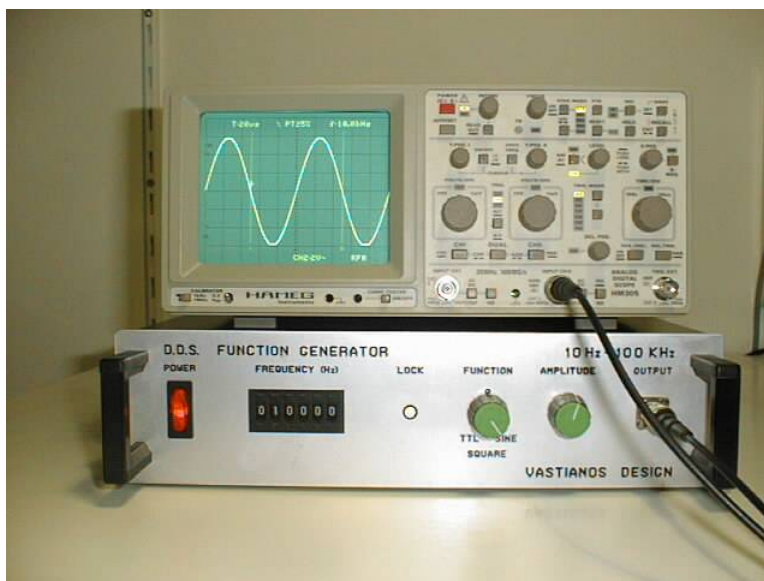


Figure 5: function generator and oscilloscope setup



2.1.2.5 Integration

The total monitor will have to integrate the LabVIEW™ program to the circuits and to the sensors. The sensors should input the data from the patient or test subject to circuit, where it will be amplified and filtered and then it will be sent to the LabVIEW™ program to clearly display the patient's current status through the use of graphs and numeric values. The circuit board will include all of the filtering and amplification. The advantages to using all electrical hardware for the signal manipulations once the circuit is build it is more robust and analog filtering and amplification provides better results. However the downfall to manipulating in the analog domain is that that all the filtering and amplification parameters are fixed, which eliminates any possibility of adjusting the parameters to optimize the displayed signal. The data is then converted to the digital domain where the signals are compiled into one DAQ assistant allowing the program to have one collaborative final output and will be able to analyze each signal simultaneously. The signal transducers will be implemented into circuit board where the data will be manipulated to reduce the noise. After the acquisition stage the input will then be ready for the LabVIEW™ program that is installed onto a Blackfin® chip. Then the display screen will have to be attached to the circuit board to allow for a clear presentation of the signals. The LabVIEW™ program will have to be either applied to a PIC chip or a Blackfin® chip to control the function of the monitoring system. The Blackfin® chip will allow for a more complex display, which will allow for more alterations on the site. The PIC chip will be more difficult to use due to its less capable abilities.

2.1.3 Design 3

2.1.3.1 Objective

The objective of this project is to create a monitor that will accurately calculate and display the consciousness level of the patient under anesthesia. Chief of Trauma Anesthesiology at Hartford hospital, Dr. Joseph McIsaac, is the main client and his needs will be considered for all aspects of this design.

This device is going to use measurements of four vital signs to determine the level of consciousness of a patient under anesthesia. Mainly the monitor will focus on the patient's physical condition, medical conditions and prior exposures. During the process of anesthesia the patient's ECG, volumetric capnography/pulse oximeter, blood pressure and their EEG signal will be recorded and analyzed. These four signals will be combined to create an accurate depiction of the patient's level of consciousness.

The subunits of the device will be considered in a high level of detail as with the original two designs. There are a variety of different components that will go into this device, and all should be carefully selected and manufactured. Perhaps the most important aspect of this device is the LabVIEW™ program that interprets the four different signals. Other subunits are important as well such as the case design and the individual transducers that will be used to test the subject's vital signs.



Instead of volumetric capnography a pulse oximeter will be used yielding essentially the same results. The LabVIEW™ block diagram has been reverted back to the original design. The design of the case has been refined to include materials choice, dimensions, and other features. In general the methods of testing and the transducers being used have been elaborated on. In the second alternative design, we discussed leakage current, and in this design we tell how to test for it and fix it if a leakage current is detected.

2.1.3.2 Subunits

The third version of the design also uses LabVIEW™ as the primary program for integration of the different physiological signals obtained from the patient. In this version of the design, the LabVIEW™ program incorporates the filtering of the transducer signals into the program itself as in the second design. In our first design, the filters were constructed as physical circuits outside of the LabVIEW™ program. Although using external filters would create less noise than those implemented in LabVIEW™, the LabVIEW™ filters are easily created and used, and can be toggled in order to keep the noise to a minimum.

In this version of the front panel, the previous drop down menu has been eliminated and replaced by individual graphs for each of the different signals as in the first alternative design. The drop down menu presented too much of a potential for complications and confusion in interpreting the graphs. If the anesthesiologist wanted to view one of the signals during surgery, he or she would have to click the drop down menu, and select the appropriate graph. In place of the drop-down menu we have included four separate graphs for the four different physiological signals, and one graph for the overall level of consciousness. The latter of the graphs will be made more prominent seeing as that is the most important of the five graphs. The individual graphs are straightforward and can be viewed easily and all at the same time on the screen. This is useful if the anesthesiologist would like to view a specific signal while still monitoring all the others including the total level of consciousness.

There are some changes made to the transducers between the previous design and this one. The main change is that the volumetric capnography signal will no longer be used in our design. In its place we have included a pulse oximeter, which essentially completes the same task. In volumetric capnography, the level of oxygen respired is used to infer the level of oxygen in the blood, and doubles as a method of measuring the volume of air respired and breathing rate. However, this method is very invasive and eliminates the Pulse oximetry used two different wavelengths of light from light emitting diodes to indirectly measure the level of oxygen in the bloodstream. This method of measuring blood oxygen saturation is non-invasive, and inexpensive. The breathing rate and volume of respired air is no longer measured, but the ease of measurement of the blood oxygen level outweighs the loss of the volumetric capnography signal.

The specific operations of the individual transducers and the testing of each respective transducer have also been refined in this updated version of the design. Biopac sensors will be used to test the device and ensure that each of the different signals is operating correctly and to



the degree of accuracy required by the client. After the transducers have been tested with Biopac, they can be integrated with LabVIEW™ and tested for final operation.

For the electrocardiograph (ECG) signal, there will be three electrodes placed on the body to measure the signal. One electrode must go on one of the subject's legs, and one on each of the subject's wrists. The electrode leads are then attached to the electrodes, with the ground on the leg. The ECG signal will be tested and calibrated using the Biopac software. Once the electrodes are receiving usable signals, the transducers can be applied to the LabVIEW™ program for final testing and implementation.

The electroencephalograph (EEG) signals will also be recorded using the Biopac software. The Biopac program will be used to test the transducer before it is applied to the LabVIEW™ program. The electrodes will be placed on the patient's head in order to measure the electric potential across the skull to determine brain activity. A third electrode must be placed on the earlobe in order to ground the patient. In order to test the patient, he/she must remain in the supine position with the head resting comfortably tilted to one side. This positioning will yield the best and most accurate results. After the electrodes are attached to the previously specified locations it must be calibrated, and after it is calibrated the transducer can be attached to the LabVIEW™ program by using the DAQ assistant. Channel one will display the raw EEG wave, channel two alpha, channel three beta, channel four delta, and channel five theta. Once the DAQ assistant gets the signals from the transducer the program can use these signals to help determine the level of consciousness.

The pulse oximeter transducer will be calibrated in a similar way. The pulse oximeter probe will be placed on the tip of the subject's finger and calibrated through Biopac. Once all the transducers have been sufficiently tested through the Biopac software they can be integrated into the LabVIEW™ program for the final device testing. The pulse oximeter was chosen instead of volumetric capnography because it is a less complicated process. To measure the levels in the blood, a pulse oximeter uses two different wavelengths of light to measure the oxygen concentration in the blood. Volumetric capnography uses a similar method, but measures the carbon dioxide level in respired air. Volumetric capnography is not particularly invasive to the patient, but if the surgeon needs to perform surgery on the head or face of the patient this method cannot be used. For this reason we chose to use a pulse oximeter because it is simply a clip that is placed on one of the fingers on either hand, so it will never get in the way of a surgeon or his/her tasks.

The case has been modified from the previous version to include a much more streamlined design. This version of the case will be molded from a polymer, specifically ABS plastic because it has good shock absorption properties and is reasonably inexpensive. The case should be appropriately sized so as to fit all the components with minimal extra internal space. It should have sufficient ventilation and fans if necessary to keep the internal components cool and the exterior should be functional and aesthetically pleasing. This particular case has an opening for the monitor to be mounted, and an area to the side of the monitor that is appropriate for mounting buttons for navigating through the device's menus. The monitor and buttons should be mounted behind a plastic film to ensure ease of cleaning, and reduce the risk of failure from any liquids or foreign materials that might come in contact with the front of the case.



Testing for leakage current is imperative in the development of a safe and effective electronic device. If leakage current is present it can result in extremely dangerous and potentially fatal current running through the metallic components of the case. If someone touches any of the exterior metal components of the case the current will be transferred to them. The second design addressed leakage current, but not how to actually test for any sort of leakage or how to stop leakage current if it is present. This version of the design addresses the specific methods involved in testing for leakage current. A leakage current tester must be either purchased from a vendor or borrowed from another institution. The tester must be used to test the external metal components and the power cord. This is done by touching a probe to all metal components, and if any current is measured there is a current leak. To test the power cord, the plug is physically plugged into the leakage current tester and the cord is rotated around the plug. The tester will give a reading when this is done if there is any leakage current. If any leakage current is found, the current must be traced back to the source. The current must then be fixed by grounding the components of the device causing the leakage.



2.2 Optimal Design

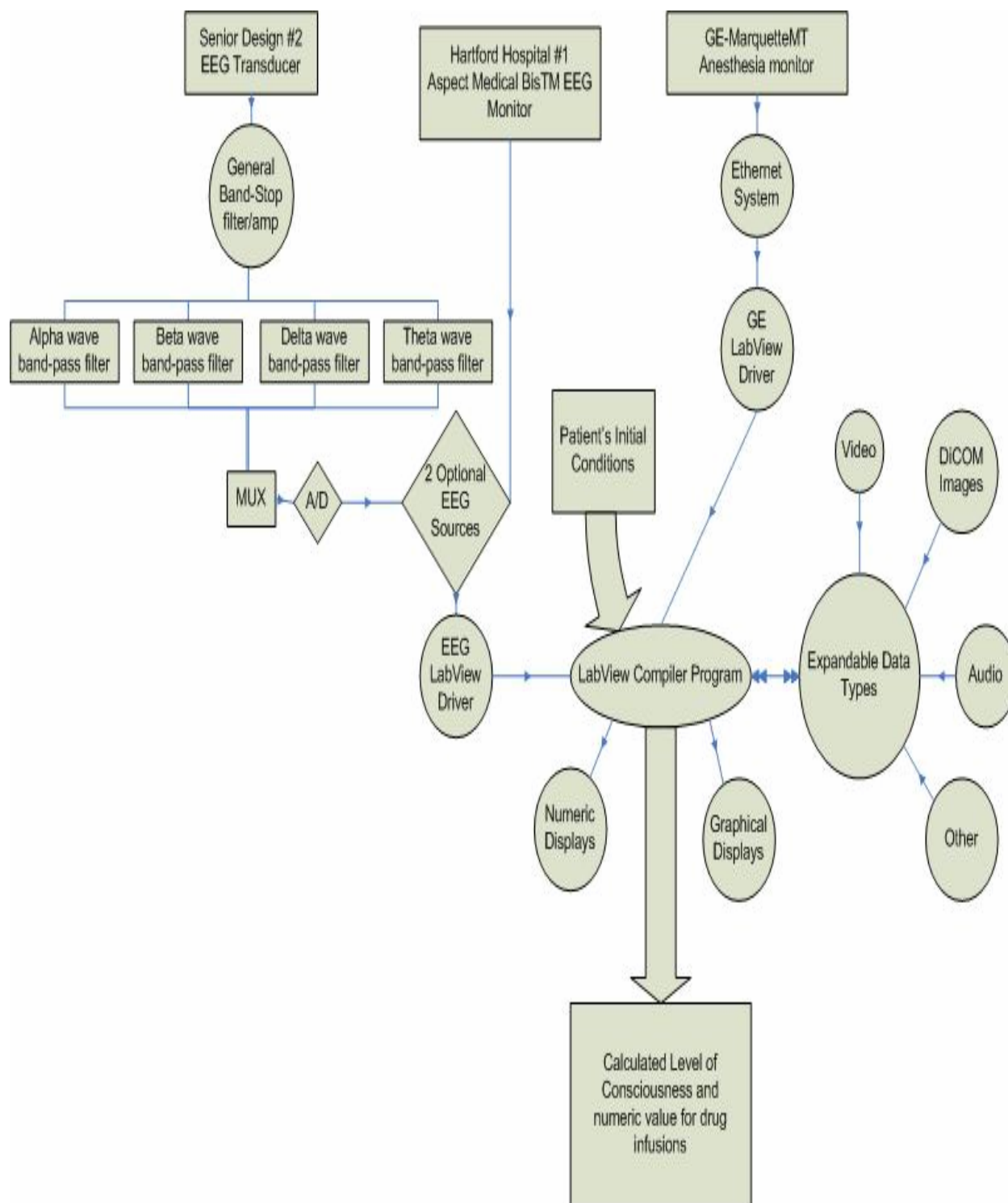


Figure 6: Optimal Design flow chart.



2.2.1 Objective

The objective of this device is to create a program that can take the information from the two other monitors and analyze them in a way to apply that information with the patient's prior information in a way to diagnose a proper dosage to keep the patient under anesthesia. The focus of this new monitor is to allow for a more sufficient measurement and time analysis of the patient's surgery. This should satisfy the needs of both the client and our advisor.

The new design started when the client told us that our design was not in the direction he had originally anticipated. Then the advisor decided that the client's requests were not adequate for the senior design class. After reinterpreting what both the client and the advisor thought was adequate for the design, the design was given a total overhaul. The new design was mostly directed by the advisor of the project, Dr. Enderle. The new object of this project had become to meet the standards set by our advisor to involve three types of engineering. The first type of engineering used is computer programming, which will be done to process the information imported from the other devices and the anesthesiologist. The next type of engineering is electrical circuits which will be done when building transducers to connect them, connecting the LCD screen, and the buttons that will be used to insert the patient's prior information which will have to be inserted manually.

This device is going to use measurements of 3 signals to determine the level of consciousness of a patient under anesthesia and find if more anesthetic needs to be applied. Mainly the monitor will focus on the data that is received from the GE-Marquette anesthesia monitor, the Aspect Medical BISTM EEG monitor, and will have to include time stamping. During the process of anesthesia the patient will have data that will be incorporated into the LabVIEWTM program, analyzed and the data in graphical form and then recommend an applied dosage of anesthesia.

This device should be reliable and easily used throughout a surgical endeavor. The settings should be easily managed allowing any level of experience technician to update them. The front panel will display clear graphs with the corresponding numerical values and appropriate labels. The device should be able to withstand a great deal of time in the surgical rooms and be durable enough to withstand everyday use. The device should have a clean and purposeful appearance in the fact that there should not be any wasted space as the device will be in close proximity of patients while maintaining accessibility without compromising the surgery. These devices have to be able to function in the hospital setting without exploding. The Aspect Medical BISTM EEG monitor has an explosion hazard which states that it should not be subjected to a flammable atmosphere or put in an area where concentrations of flammable anesthetics may be. It is also not designed for an MRI environment. These restrictions will continue to the new expert anesthesiology monitoring system.

This design is slightly different than the last because the imported signals will be data received from the GE-MarquetteTM anesthesia monitor and the Aspect Medical BISTM EEG monitor and displaying it on a LabVIEWTM program that will be able to manipulate the received data, time stamp it, and correlate it to a dosage of anesthesia for the patient.



2.2.2.1 LabVIEW™ Program

2.2.2.1.1 Front panel

The front panel for this design has a few preliminary aspects that need to be addressed. The main focus of the front panel is to have a clear graphical and numerical display of the most important data. The graphs will display a time stamped version of the data that will be imported from the different devices that are required. The graphs will then be used to analyze the incoming data and then applied to a diagnostic analysis of patient's consciousness. The patient's information will be applied to the level of consciousness and then used to help determine the correct dosage of the anesthetics. The graphs will be colorful in a way that will allow for color segregation between graphs which will allow for the doctor to quickly look up and know exactly where the patient is and will require little to no additional adjustments during a time of emergency. The numerical values that will be displayed to show the level of consciousness of the patients will be large and clearly displayed next to their corresponding graph. The level of consciousness will be determined using a level of fuzzy logic that will synthesize and analytically presented for the anesthesiologist. Figure 7 shows a rough estimate of the visual appeal of the front panel.

The patient's information must be easily manipulated on the front panel by the anesthesiologist. These factors consist of the patient preliminary statistics based on their prior resistance, acute and chronic disease states, age, weight, gender, exercise tolerance, medication usage, and habits such as smoking, drug and alcohol use. These will all have to be configured neatly and clearly on the front panel so that the anesthesiologist can alter these during the procedure if necessary. There is a chance that a patient may lie to the doctors and the information given maybe wrong for one reason or another. This is why it is necessary to make the preliminary statistics easily manipulated, and ensure the program is not completely dependent on these factors.

The front panel will have to be easily understood in a time of complete emergency. This means that there can be no room for misunderstanding by the doctors in the surgical room. The preliminary design for the adjustment of each of the patient's preliminary information will be set up right next to their corresponding values on the screen and the doctor will be able to rotate the dial clock wise for a higher value, or counter clockwise for a lower value. These processes will have to be clearly labeled and will show the manipulation direction right on the dial.

The front panel will have three main graphs displayed with time stamps. The first graph will be the imported value for the GE-Marquette™ anesthesia monitor, the second will be a display of the Aspect Medical BISTM EEG monitor and the third will incorporate both of these data sets into a single graph that will display consciousness and then recommend the proper dosage of anesthetic to be administered by the anesthesiologist after considering the patients prior information.

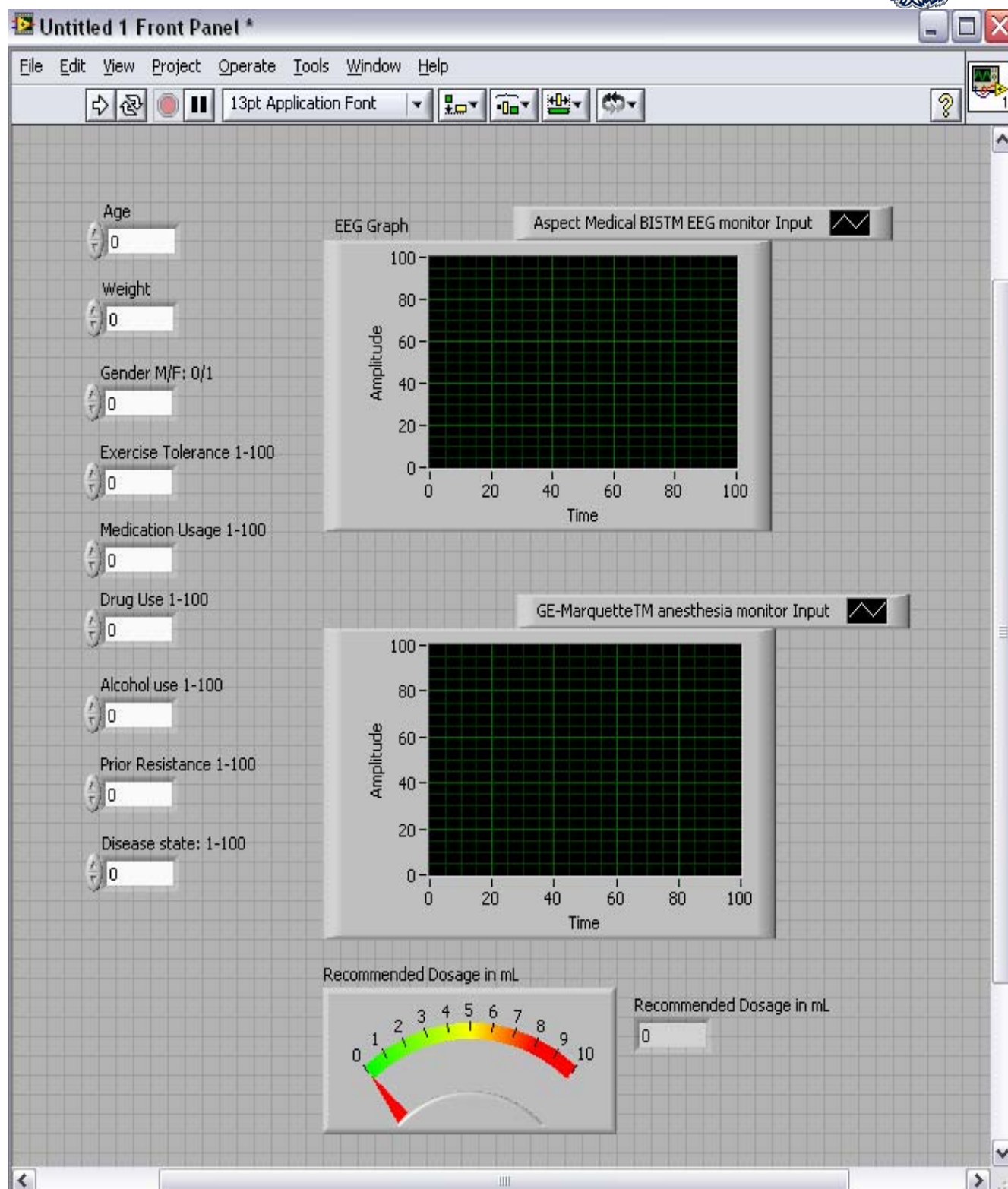


Figure 7: Example front panel of the anesthesia monitoring system



The main model for the front panel is being compared to the Aspect Medical Systems BISTM VISTA or GE anesthesia machine the BISTM monitor as displayed in figure 7. The BISTM monitor relies on a clear graph of an Electroencephalogram (EEG) to determine the level of consciousness of a patient at a moments notice by the anesthesiologist and then displays a number between 1 and 100 that corresponds to their consciousness. The BISTM monitor also highlights an acceptable region to which the patient is within the correct level of consciousness for the surgery to continue without amnesia, analgesia, and immobility becoming a factor. There is also an alarm that will sound if the patient exceeds the previously determined range to alert the anesthesiologist of the patient approaching brain damage or a waking state.

The data will be imported from the data that is imported from the Aspect Medical BISTM EEG monitor and displayed in a similarly clear and obvious manner on the LabVIEWTM front panel. The data will be the same with a time stamp and an implemented analysis graph that allows for a diagnostic volume of anesthetic to be applied to the patient.



Figure 8: BISTM Vista monitor



2.2.2.2.2 Block Diagram

The block diagram for the program will be aimed to meet the code followed by national instruments programmers, which consists of common rules to pursuing a proper program. The program should be clear and easily manipulated. The titles of all the different parts of the program are necessary when working with the program and problem shooting. The DAQ must be used in a manner that allows the program to take different inputs and apply them all to one block diagram.

The block diagram is going to have a case structure that will allow for the calculations of the data in a way that will help to present the data graphically with time stamps clearly. The block diagram will be able to present the graphs after they have been properly filtered and adjusted for LabVIEW™.

The block diagram will include global variables that will be placed outside the main loops. This will allow for the numbers to be manipulated at any point in the device's process. Each of these separate loops can be recalled and used in multiple places in the program making the information easy to work with. The patient's prior information will be incorporated into this section as to allow for easy manipulation without program hindrance.

The block diagram will have to incorporate the two signals from the different sources into one clear presentation of graphical data and analytical values. The value will represent that total consciousness of the patient. There will be calculations done involving the patient's information and the level of consciousness read by the devices that will be used to determine the correct application of dosage that should be applied to the patient.

The patient's prior information will effect the equation for the calculation of the administered dosage of anesthetic in the following ways. The patient's age will create a more sensitive and lower dosage quantity to make sure that the child's dosage will not be over shot and put the patient into a lower region. This will be similar to the effects applied if the patient is older. Next the patient's weight will have an extremely strong effect on the patients dosage application. If the patient is heavy then there will be a much more dramatic dosage applied to allow for the fact that the patient has more blood to move through before the anesthetic reaches the brain. On the contrast if the patient is much lighter the dosage will be decreased as to not over medicate the patient. If the patient is a male then there will be a higher natural tolerance to the anesthetics and more will be applied per weight. The more athletic the patient the slower their body is going to be processing and working while in the resting state. This means that less anesthetic will be applied to a more athletic person. Medication usage is a huge factor in determining the amount of anesthetic applied. If the patient has prior resistance to anesthetics or other similar medications then the normal applied amount will need to be greatly increased. Recreational drug use can also have an effect on the patient's resistance. This can also show a steep decrease in the effects of the anesthetic and more will have to be applied to this type of patient. If a patient has an alcohol problem, there organs could be weaker and therefore slow down the processing of the anesthetic and more of the anesthetic may not be able to get to the patients brain and more will have to be applied. If a patient is in a state of disease and is already



in a weakened state then the anesthetic may slow down already struggling organs and cause more problems so the dosages will be decreased as well.

An example of a block diagram that fits the requirements that we are looking to pursue is shown as figure four. This diagram is clear, well labeled, and organized in an easily followed manner. This is extremely important in creating a good environment for fixing and accessing problems that may arise during testing or even during later uses. There are flaws that tend to escape the grasp of the testing atmosphere and are only discovered when the device is used in the actual application it was designed for. These errors will have to then be examined and corrected after the device has been cleared for use. This might mean someone unfamiliar with the design may have to navigate the block diagram, find the error, and reprogram the section. If the block diagram is impossible to follow this job becomes immensely more difficult.

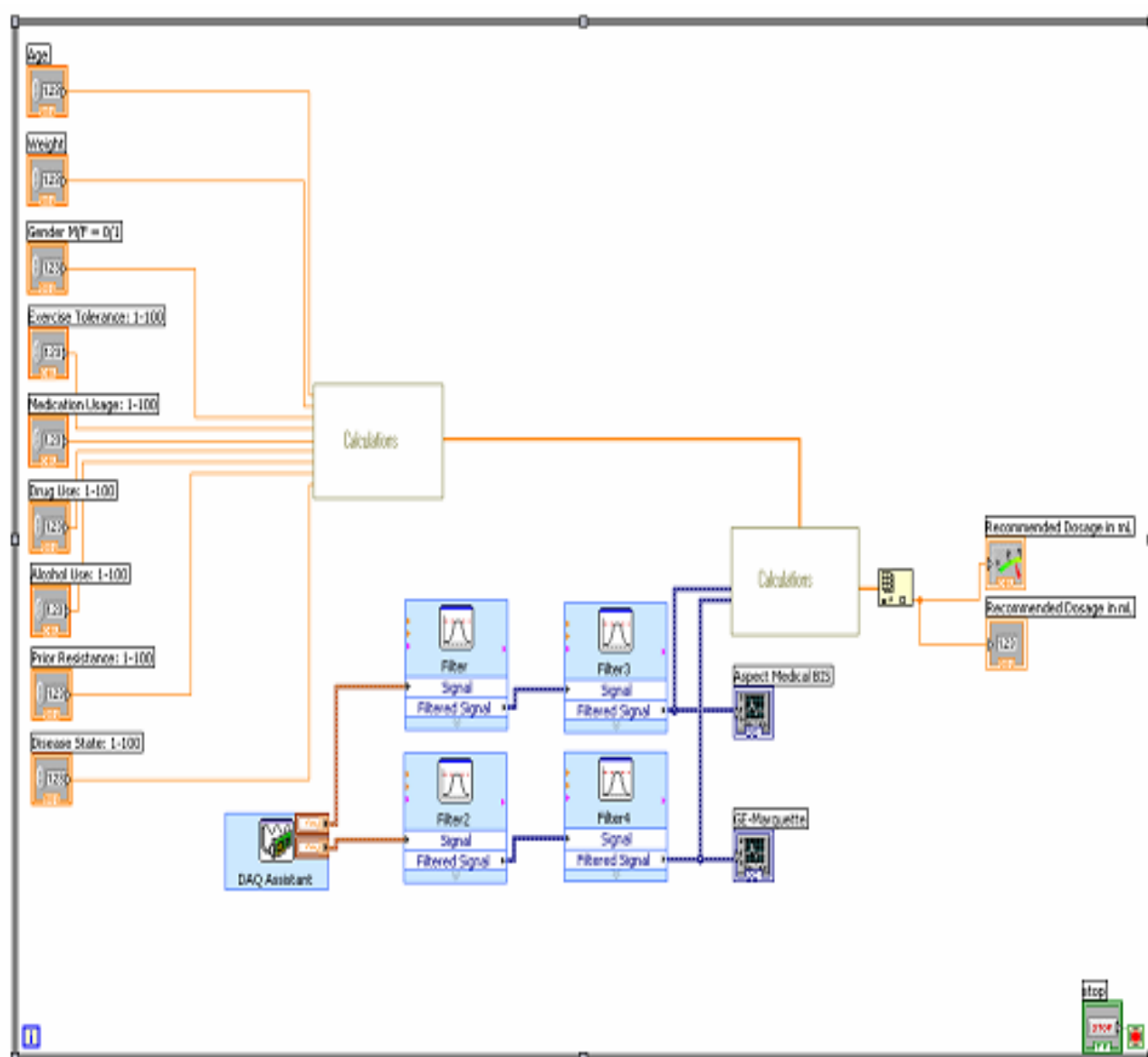


Figure 9: Example of a well designed block diagram



The signal received from the GE-Marquette™ anesthesia monitor will have multiple readings that will be exported from the device and imported into the expert anesthesia monitoring system. These signals will then be processed and filtered as to allow them to be separated out into separate graphs on the expert anesthesia monitor and then analyzed and time stamped. This data will be used to determine a level of consciousness of a patient, filtered and clearly displayed on the expert anesthesia monitor and then used to help determine the proper dosage to apply to the patient.

The signal that will be retrieved from the Aspect Medical BIS™ EEG monitor will be based primarily off of an EEG wave form. This signal will be exported through a transducer, the noise will be removed and the wave will be filtered and reconfigured on the expert anesthesia monitoring system. Some noise will be entered into the machine due to thermal vibrations, actual sound waves and other imperfect connections that can be filtered out. This signal will then be filtered, analyzed and displayed on the front panel of the expert anesthesia monitor. This data will then be used to determine the proper dosage of anesthesia to apply to the patient. The three portions, the GE-Marquette™ anesthesia monitor, the Aspect Medical BIS™ EEG monitor and the patient's prior information will be added and processed to determine the proper dosages. The BIS™ monitor allows the user to select between a filtered EEG signal display and a raw data version.

2.2.2.2 Connectors and their testing

A transducer is a device that converts a signal of a certain type into an electric signal that can be read by a different device. Examples of transducers are speakers, microphones, pH probes, thermocouples, and strain gauges. For this application the transducers will need to be able to be read by our printed circuit boards and the microcontroller(s). This device will need a transducer for each of the four vital signals. The blood pressure transducer will be an intravascular pressure catheter that will be used to constantly record blood pressure. The EEG and ECG transducers will both be biopotential transducers used to measure the change in potential on the skin based on the electric activity of the brain and heart.

There will be two main connectors that will have to be developed and designed for this monitoring system. The first transducer will have to be able to transfer connect to the port in the GE-Marquette™ anesthesia monitor that will then be able to attach into a port in the case of our monitor that will then be connected to the black fin chip directly. The transducer will have to be able to maintain the signal with as little signal loss and noise added as possible. This transducer will have to be able to have an attachment to the black fin chip.

The second connector will have to be able to transport the signal of the EEG and the patient's level of consciousness from the Medical BIS™ EEG monitor and transfer it safely without addition of noise to the black fin chip within the case of our expert anesthesia monitoring system (EAM). The transducer is going to have to be easily attached and detached from the other monitors so that data can be just inserted from any device. This monitor has a few options for the extraction of the data. The transducer can hook up to either a serial port, USB port type A or type B. The BIS manual suggests using the USB port type A as the output source. The BIS™



monitor can export data in a live format through the transducer which and be received by the EAM where it can be processed and used. The BISTM can store up to 400 hours of monitoring which can be exported into the EAM where it will be time stamped and processed.

The Aspect Medical BISTM EEG monitor has a serial port that will be used to create the connection between our monitor and the BISTM. This port is an A-2000 serial port which is a asynchronous serial communications port with signals equivalent to RS-232 levels. The port happens to be a DB-9 female connector which is wired as a DCE. This female connection is shown and labeled in figure 10.

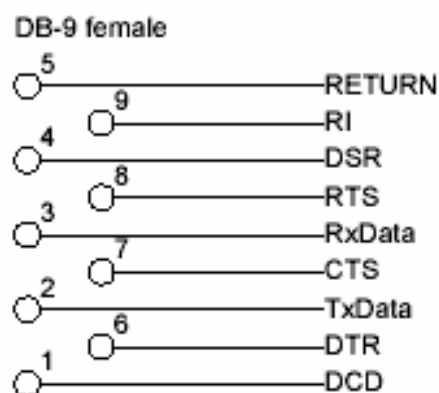


Figure 10: female port for BISTM Monitoring system.

When anything is connected to this port the equipment must be checked for leakage current to make sure that there is less then the IEC601-1-1 limit. If the connection does not meet the requirements then there could be a chance for explosion that would be to risky to allow the usage of the connector.

To wire the cable to a 9-pin D connector a “straight” (modem) cable has to be wired using figure 11. If the connection is fitting to a terminal with a 25-pin D connector, a cable must be used such as figure 11. The serial port settings are displayed in figure 11.

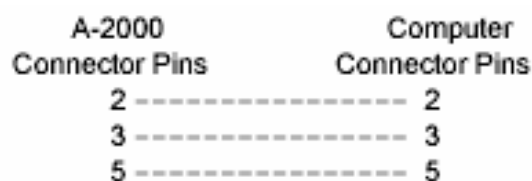


Figure11: 9-pin D connector.

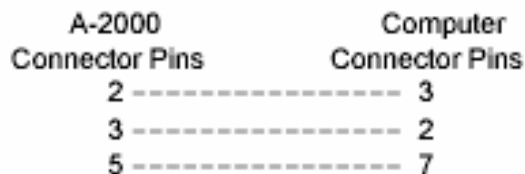


Figure 12: 25-pin D connector.

	ASCII Protocol	Binary Protocol
Baud Rate	9600	57,600
Data Bits	8	8
Stop Bits	1	1
Parity	No Parity	No Parity

Figure 13: Physical characteristics of the port.

For new data acquisition programs such as our expert anesthesiology monitor, Aspect recommends that the data set should use a combined channel that will be able to support other 2-channel sensors. The A-2000 serial port allows three different Bispectral Index values, which allows for one of them to be displayed. BISTM has three variables that are outputted in Binary protocol, the bispectral_index, bispectral_alterate_index, and the bispectral_alterate2_index, which are transmitted, but only the bispectral_index should end up being displayed. The A-2000 can transmit through the bispectral index based on a artifact-free epoch of data, where each epoch is a 2 second piece of data. If the signal quality index is good or between 50% and 100% then the BIS number is displayed using “solid” digits and is trended. This means that the signal is good and the data is totally reliable. If the data comes in at less then 50% then the numbers will be displayed using “hollow” digits, and a “hatched” artifact bar will be drawn at the bottom of the trend graph. If the quality is bellow 15% then there will be no numerical display and a solid artifact bar will be drawn at the bottom of the trend graph. This function allows the BIS to determine the quality of the signals that are being processed in the system.

The A-2000 will begin to transmit data records, one every five seconds, immediately after the header record is sent. The data record that is sent always starts with the date and time. Then the EEG variables are sent and the artifact flags are right-justified decimal numbers. The impedance values are measured in kOhms. The filter has an off and on string. It also has a string that allows a display of what level the alarm is activated on, none, high, or low. An example is displayed in below.



Example:

```

TIME          |DSC      |PIC      |Filters |Alarm  |Lo-Limit|Hi-Limit|Silence |
SR09  |SEF06  |BISBIT00|BIS     |TOTPCW06|EMGLCW01|SQI07   |IMPEDNCE|ARTF2  |
SR09  |SEF06  |BISBIT00|BIS     |TOTPCW06|EMGLCW01|SQI07   |IMPEDNCE|ARTF2  |
SR09  |SEF06  |BISBIT00|BIS     |TOTPCW06|EMGLCW01|SQI07   |IMPEDNCE|ARTF2  |<CR><LF>

```

When the two header lines are aligned, they should look like this:

```

S HDR3          |SYS 3.00|
TIME          |DSC      |PIC      |Filters |Alarm  |Lo-Limit|Hi-Limit|Silence |
Ch. 1
SR09  |SEF06  |BISBIT00|BIS     |TOTPCW06|EMGLCW01|SQI07   |IMPEDNCE|ARTF2  |
Ch. 2
SR09  |SEF06  |BISBIT00|BIS     |TOTPCW06|EMGLCW01|SQI07   |IMPEDNCE|ARTF2  |
Ch. 12
SR09  |SEF06  |BISBIT00|BIS     |TOTPCW06|EMGLCW01|SQI07   |IMPEDNCE|ARTF2  |<CR><LF>
SR09  |SEF06  |BISBIT00|BIS     |TOTPCW06|EMGLCW01|SQI07   |IMPEDNCE|ARTF2  |<CR><LF>

```

Figure 14: Code to alarm

```

01/23/2001 12:34:56|      8|      4|On   |None  |Off   |Off   |No     |
100.0| 28.6| 0000| 45.6| 21.7| 24.3| 0.8| 18|10000020|
100.0| 28.6| 0000| 13.9| 9.3| 22.9| 0.8| 1|10000020|
100.0| 28.6| 0000| 29.3| 15.5| 23.6| 0.8| 0|10000020|<CR><LF>

```

Figure 15: Code for alarm heightening.

The impedance records are sent only when the sensor checks or continuous ground check are on. Each of these recordings will start with a string called “IMPEDNCE” which also includes date, time, and impedance values for 2 channels. Each the ground, the positive and the negative electrodes all pass separate records. All impedance values are right-justified decimal numbers and non-numeric strings called “LDOFF” or “NOISE” and have a prefix of positive, negative, or ground for a label. An example of this is shown in below.

```

IMPEDNCE|01/23/2001 12:34:56|+ 5000|+ LDOFF<CR><LF>
IMPEDNCE|01/23/2001 12:34:56|- NOISE|- 12000<CR><LF>
IMPEDNCE|01/23/2001 12:34:56|g 50000<CR><LF>

```

Figure 16: Code for Noise.

Error records can be identified by their unique labels in front of the code of “ERROR” or “CLEAR”. The error message usually contains an actual message about the error. The clear function that tells you a error message that should be deleted. Examples of these two errors are found below.



```
ERROR    |01/23/2001 12:34:56|DSC Not Connected {E01}<CR><LF>
CLEAR    |01/23/2001 12:34:56|DSC Not Connected {E01}<CR><LF>
```

Figure 17: Code for error messages.

There is also a Version number record which can state every update and all of the software that is being used by the monitor at that time. This allows a quick and easy availability to the updates that have been processed on a certain system. An example of this display is shown below.

```
VERSION |01/23/2001 12:34:56| 3.00| 3.00| 1.13| 1.07| 3.00| 2.00|C012345 <CR><LF>
```

Figure 18: Code to find version number and updates of software.

Record events have to be enabled to be used and once they are enabled the user marks an even on the A-2000. An example of this message in the on position is as follows.

```
EVENT    |01/23/2001 12:34:56<CR><LF>
```

Figure 19: Code to activate recording of events.

Commands can also be run through the connection to the BISTM system. The A-2000 BISTM monitor can be run and small controls can be sent to it via the serial port such as the ones in the following table.

Commands	Code (ASCII)	Description
Clear All Output	C (0x43)	Turns off all output.
Header Request	D (0x44)	Causes A-2000 to transmit Header Record and begin transmitting Data Records (default).
Error Records ON	E (0x45)	Turns on Error Record output.
Error Records OFF	e (0x65)	Turns off Error Record output (default).
Event Records ON	N (0x4E)	Turns on Event Record output.
Event Records OFF	n (0x6E)	Turns off Event Record output (default).
Update Output ON	U (0x55)	Turns on all output.
Version Request	V (0x56)	Transmits A-2000 software revision numbers.
Impedance Records ON	Z (0x5A)	Turns on Impedance Record output.
Impedance Records OFF	z (0x7A)	Turns off Impedance Record output (default).

Table 2: Important Code.

When a message is received from the A-2000 BISTM monitor to an external device it comes in a unique message ID. Some of the possible data acquisitions that are going to need to be processed will be received in the format displayed in these tables.



Description: Processed EEG data from EEG snippet.

Field	Possible values or format of data in the field
Message ID	1106
Length	EEG_SNIPPET_PROCESSED_DATA_LEN
Message dependent data	struct snippet_processed_vars_msg - Refer to description in Appendix A.

Table 3: processed EEG Data From EEG snippet code.

Description: Header information for EEG snippet.

Field	Possible values or format of data in the field
Message ID	1104
Length	EEG_SNIPPET_HEADER_DATA_LEN
Message dependent data	struct snippet_info_msg - Refer to description in Appendix A.

Table 4: Header information for EEG snippet code.

Description: Processed variables and spectra sent to the Host once every second.

Field	Possible values or format of data in the field
Message ID	53
Length	SIZE_M_PROCESSED_VARS_AND_SPECTRA
Message dependent data	struct processed_vars_and_spectra_msg - Refer to description in Appendix A.

Table 5: processed variables and spectra sent to the host once every second code.

Description: Raw EEG data in 16-bit two's complement signed integer format. The data is interleaved, i.e. the first integer is an EEG value for channel 1, the second integer is the corresponding EEG value for channel 2, the third integer is another EEG value for channel 1, etc.

Field	Possible values or format of data in the field
Message ID	50
Length	$4 + ((\text{rate}/8) * \text{numofchan} * 2)$
Message dependent data:	
2 bytes - unsigned short numofchan	2
2 bytes - unsigned short rate	128 or 256
Remaining bytes:	EEG data in 16-bit two's complement signed integer format.

Table 6: Raw EEG data code.



Description: Contains BIS History data records.

Field	Possible values or format of data in the field
Message ID	1110
Length	Variable – multiple of 12 bytes, up to MAX_BIS_HISTORY_DATA_LEN
Message dependent data	struct history_data msg – Refer to description in Appendix A.

Table 7: contains BISTM history data records code.

Description: Indicates that an event was marked on the A-2000 at the time specified.

Field	Possible values or format of data in the field
Message ID	1115
Length	EVENT_MSG_DATA_LEN
Message dependent data	ASCII string (see Section 4.1.6).

Table 8: Code to indicate an event was marked.

These connectors will then have to be run through the same input Ethernet tip. This either net tip can then be attached to the black fin which will then be able to run the program that will time stamp the incoming information and use the patient prior information to determine the actually calculation of the dosage required.

2.2.2.3 GE Marquette and ADI Blackfin[®] Processor

2.2.2.3.1 GE Marquette

2.2.2.3.1.1 Hardware connections

Connecting the Expert anesthesia monitoring device will require one of two setups. First is the direct method for connecting to the monitor's ASYNC COMM port and the second is the more convenient method which involves connecting to the ASYNC COMM port on the tram-net Hub. The collected data will be the same so either method will be sufficient. Acquiring this data will require a programming language to interface and collect the data from the ASYNC COMM port. The optimal language for interfacing is ANSI standard C. For this project we will use LabVIEWTM and then compile it into a C program. To coordinate activities between the GE Marquette device and the project's device a communication software library with a serial connection will need to be implemented. Physically connecting the two devices together will be two elements. One will be the RS422 adapter with the transfer capability of 9600 bits per second and the ASYNC COMM cable with the correct pin setup. The Tramscope Monitor ASYNC COMM port requires a 9-pin cable or a 25-pin cable for connecting to the Tram-net hub.



2.2.2.3.1.2 Acquiring data

To successfully obtain data from the GE-Marquette monitor device a request packet must be sent to the monitor. This provides instructions for the program to acquire the data from the ASYN COMM port. The request packet is based on the SBEDSIDE_MSG_DEF structure and this structure is defined in the bedmsg.h file. Bedmsg.h file defines the structure and symbol definitions for the network and ASYNC COMM port communications packets. These files need to be implemented because the monitor acts as the server entity in a client/server environment. The Expert Anesthesia Monitoring device will query the GE Marquette device and the data will be transmitted to monitoring device. As mentioned before the query is in the form of the request packet.

2.2.2.3.1.3 Data Communications

The two packets, request and response, are formed in the same way. The only difference is the internal information. The response packet is larger in most cases because it carries the patient's data. Successfully interpreting these data packets means identifying the data structures and files necessary to construct or parse a packet. The LabVIEW™ program will be able to identify these elements providing an easy method for analysis.

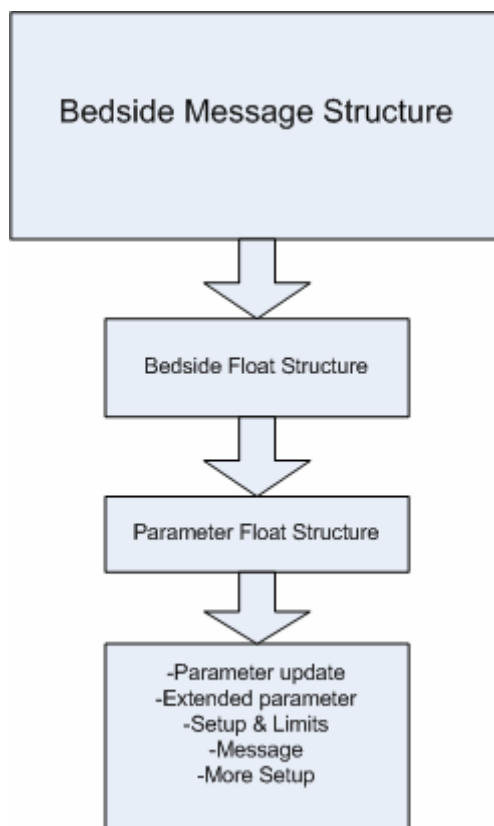


Figure 20: Block Diagram explaining outline of the parameter update packet



The data packets consist of multiple elements which describe a variety of different parameters. The bedside message structure provides the packet with the source and destination locations. The float structure organizes the information pertaining to patient monitoring such as alarm state, alarm level, patient admission, and graph status. This structure states the number of parameters collected for the parameter data array. The parameter data is organized through the use of a file called TRSERIAL.H. This file arranges the data into each data structure and provides instructions for interpreting the data within the packet.

2.2.2.3.1.4 Data Parsing

Initially the communication software strips off the UDP/IP shell and presents the bedside message. Using the SBEDSIDE_MSG_DEF structure from the BEDMSG.H file determines the destination, source, function to be performed, and the amount of data, if from a response packet. The Bedside float structure is parsed according to the SBEDSIDE_FLOAT structure. This structure is explained in the BEDMSG.h file and covers the device status data and the number of parameters in the subsequent data array. The parameters are based on a variety of signals such as ECG, BP, and CO. The parameters in the data array are then accessed and data contained within this array are used to extend and update the initial parameters. All of these commands are regulated by code which specifies which actions should take place. For example the code associated with accessing the data array and the data contained within it is found in the SPAR_FLOAT. This code is as followed.

```
Typedef struct spar_float
{
    struct PAR_IPD par_upd;
    struct EXTENDED_PAR_UPD ext_par_upd;
    struct SETUP_N_LIM setup_n_lim;
    struct PAR_MSSG_S par_mssg_s;
    struct MORE_SETUP more_setup;
    UTINY par_type;
    UTINY parcode;
    UTINY pos;
    UTINY dummy;
} SPAR_FLOAT, *pSPAR_FLOAT;
```

Figure 21: Code for a data array.

The parameter data in the preceding code structure is contained within five structures; PAR_UPD, EXPTENDED_PAR_UPD, LIMIT_VALUES, MORE_SETUP, and PAR_MSG. These data structures are provided with two 8-bit values allowing a greater variety of data analysis. The code continues through each section of the Data packet until all elements have been removed. The type of data removed is dependent on the source location. If the data was obtained from the respiration transducer then it is parsed differently than if obtained from the ECG.



2.2.2.3.2 Blackfin®

The Blackfin® processor will be used to run the expert anesthesia monitoring LabVIEW™ program. This processor is capable of high performance signal processing and efficient control processing capability which opens the chip to a variety of new applications. The Blackfin® processor contains dynamic power management (DPM) which will enable us to specify the device power consumption profile. Blackfin® also uses mixed 16/32bit instruction set architecture and development tools which ensure minimal time and produces maximum results.

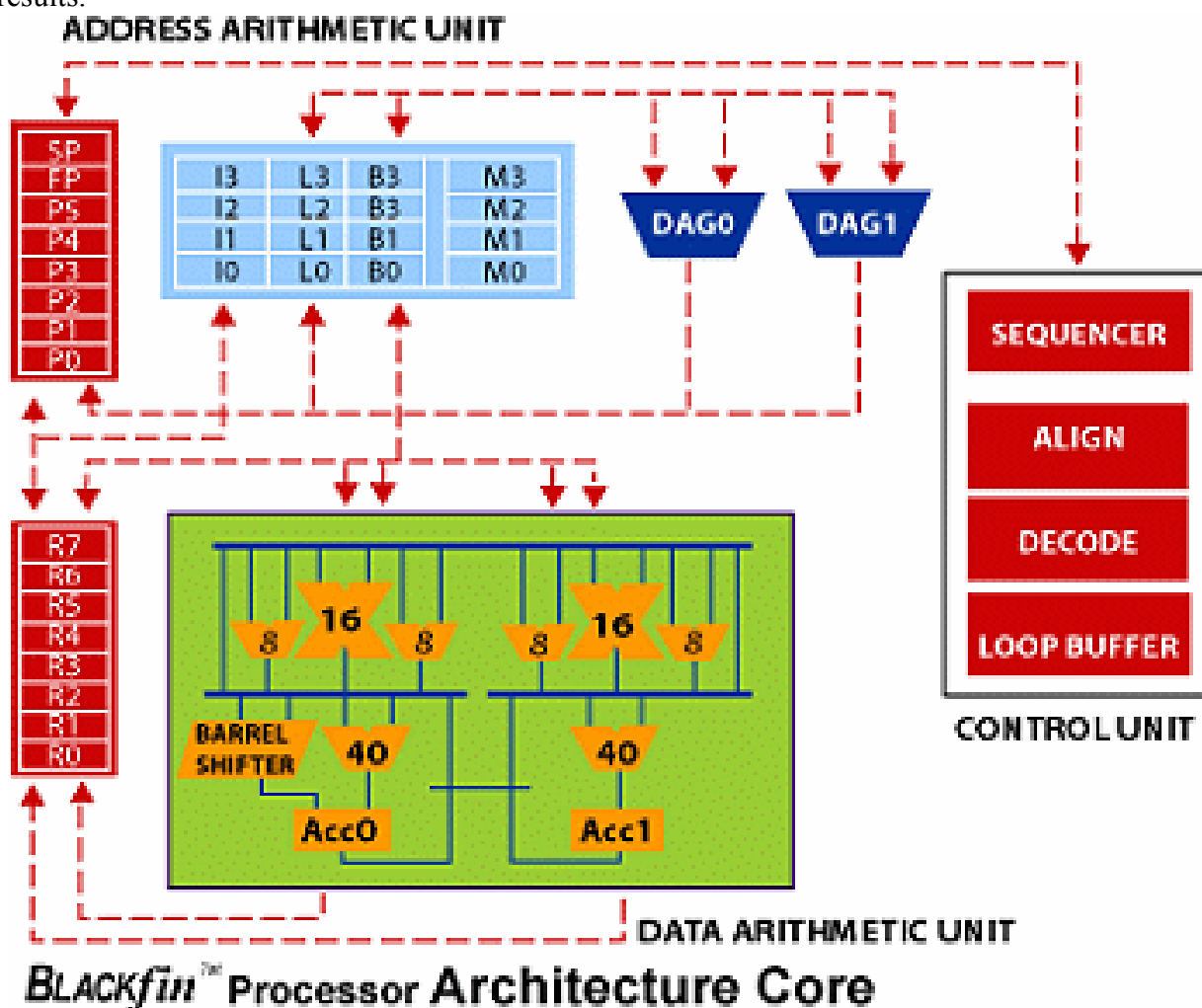


Figure 22: Architecture Core

Using Blackfin® with LabVIEW™ will provide us with fully integrated debugging capability. This combination enables trouble shooting support due to the fact that Blackfin®'s are integrated with VisualDSP++ compiler, linker, and debug connection allowing step by step processes through the graphical code and simultaneous visualization of the embedded code within the debugger. This trouble shooting support will optimize our time and provide us with an efficient way of developing accurate code.

A key concept for successfully debug a Blackfin® & LabVIEW™ program is through using breakpoints and probes on the block diagram. A breakpoint stalls the program allowing



you to manually move through the code which should allow the user to easily analyze the program. Unlike breakpoints, Probes allow the program to run all the way through however they display the corresponding numeric value passing through the virtual wire.



Figure 23: *Blackfin insignia.*

Blackfin[®] uses 32-bit RISC instruction set and dual 16-bit multiply accumulate(MAC) digital signal processing functionality, and 8-bit video processing. Blackfin[®]'s processing capability removes the need for individual digital signal and control processors this reduces material costs and simplifies hardware as well as software. Blackfin[®] processors are capable of handling asynchronous and synchronous interrupts making it suitable for embedded operating systems.

The Blackfin[®] processor can be used as dual-core devices enabling the processing of individual tasks. For our project we will use the dual-core processing to display real-time data obtained for the BIS[™] monitoring device and the GE-Marquette[™] device and running in parallel will be the processing of the data to generate the patient's level of consciousness as well as calculating the advised drug dosage.

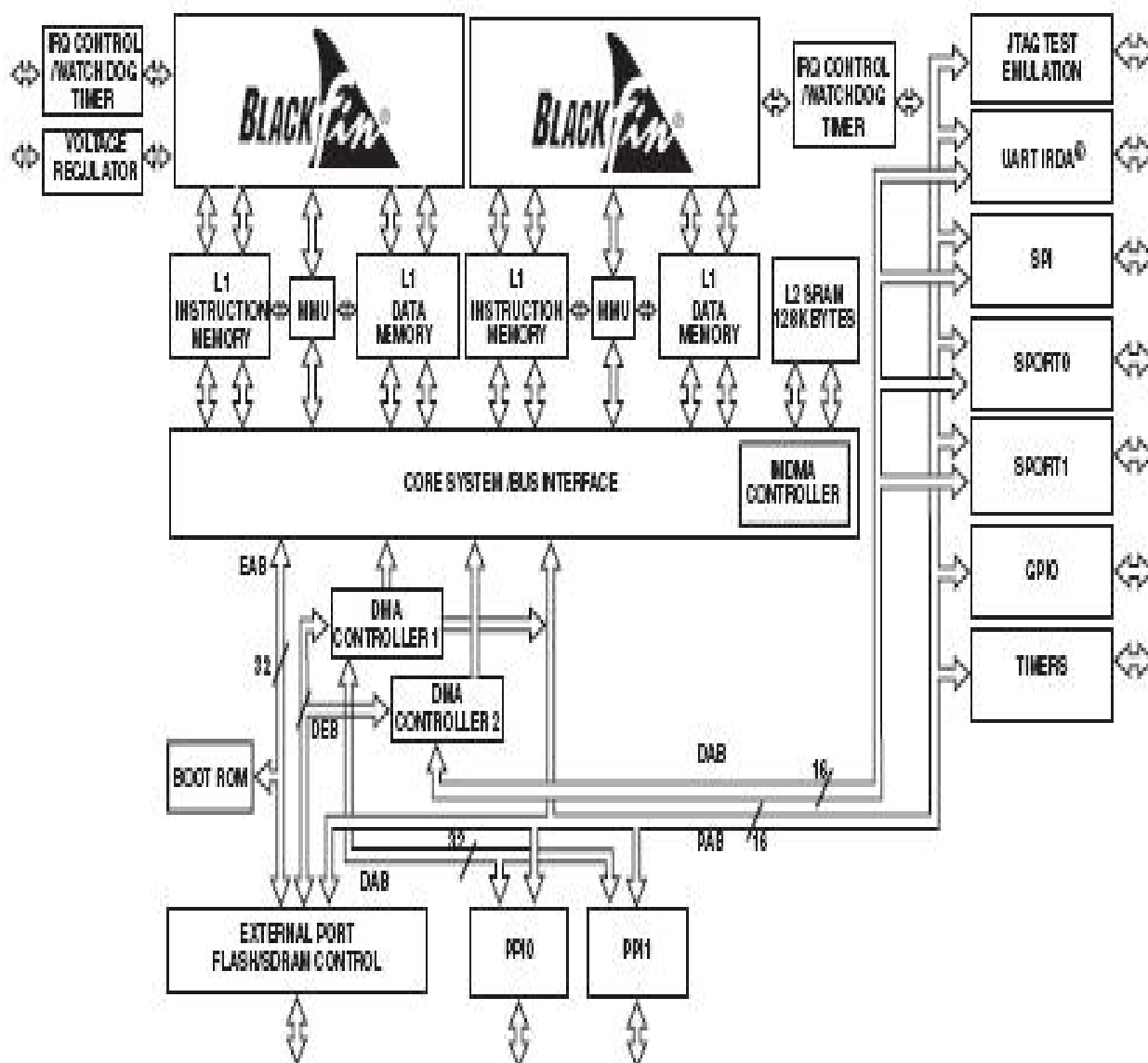


Figure 24: Block Diagram of the Dual-Core

The Blackfin[®] has a low power consumption option where the Blackfin[®] chip can still be run effectively while only consuming half the power of its closest competition. This Blackfin[®] feature is useful in applications where the device is unable to connect to a power source. What it does is manage the power consumption to the minimum power needed to run efficiently.

The methodology to develop and implement our Blackfin[®] chip into our device will be broken into 3 different stages: simulation, evaluation, and emulation. The simulation stage will occur prior to receiving. The simulation will mimic the behavior of the Blackfin[®] DSP chip. The program that will be used is VisualDSP++ which will be build around the simulation target



allowing us to build, edit and troubleshoot. Simulating before the Blackfin[®] chip is received will minimize implementation of the code onto the chip. Once the simulation is working correctly stage 2 will begin which involves using a test Blackfin[®] chip called EZ-kite lite, shown in figure 25:



Figure 25: EZ-KIT lite from Analog Devices, Inc.



This independent Blackfin[®] chip will directly connect to our PC and we will be able to verify the functionality of the chip with our program. We will be able to monitor the processors behavior even before our actually chip and circuit board arrive. Incorporating the LCD screen into our anesthesia monitoring devices will require a Blackfin[®] EZ-extender because we want to test the total functionality of the Blackfin[®] chip as it will be setup for the final design we will need to test the LCD compatibility. What this extender chip will do is it will plug into the EZ-KIT lite and allow us to test our target application of implementing a LCD display device. Also this will allow us to later test other inputs such as audio and visual inputs such as Dr. McIsaac suggested. Figure 26 is an example of the Blackfin[®] EZ-extender.



Figure 26: Blackfin EZ-extender

Once the final board arrives the code will be tested using a JTAG emulator, this is the hardware that interacts with the PC and the newly developed board which includes the Blackfin[®] chip. We will use the emulator to download the software to the chip and then communicate with the chip and display the DSP performance resulting from our code.

2.2.2.4 Patient's Prior Information

While considering prior resistance, acute and chronic disease states, age, weight, gender, exercise tolerance, medication usage, and habits such as smoking, drug and alcohol use a patient has had prior to the anesthesia the average range for vital signs will be much more readily available. These estimates will increase or decrease the alarm levels of the patient by determining the amount that the person's vital signs will be affected by these prior experiences. For example if the patient is between a certain age range the upper limit will be lowered because



the anesthesia drugs will have a stronger effect on them. Some of the personal information used will have a stronger effect than others, such as weight and prior drug use. The main problem with using information given by the patient is that the patient may lie about some information due to a fear of punishment. If a patient has prior experiences with pain killers they may be more likely to need more drugs to keep them at the correct consciousness level but they may not tell the anesthesiologist for fear of persecution. When the anesthesiologist realizes that the drugs are not causing the amount of anesthesia that they are supposed to, it may be appropriate to change the prior drug usage to a higher level to account for this resistance during the procedure.

Each of the numerical equivalents that will be given to the anesthesiologist prior to the surgery corresponding to the information required for the expert anesthesia monitoring system will be used to add to the dosage given to the patient. Usually the dosage applied is a guess and check type of fuzzy logic used by the anesthesiologist. This method for the dosage used by the expert anesthesia monitoring system will give more of a numerical calculation on the spot to support the anesthesiologist. The patient's information will be taken in and used to find an estimate of the amount of drug that should be applied. There will be a neutral or starting dosage that the anesthesiologist will supply. Then this number will be altered depending upon the patient's information.

The patient's age would affect the dosage because depending on the age gap the patient may need more small doses or maybe they can handle one larger dose. The age's will be placed into applicable ranges that will be able to diagnose more stringent dosages or more relaxed dosages. If the patient is between the age gap of 10-12, then the dosages applied may be more frequent with less medication. They also may be severely dropped down into a much lower range of applied dosages until more trial and error can be done and the correct neutral point can be set for the patient. If the patient is in the area of 25-35 there will be a more relaxed dosage given that will be able to bring the patient straight to the desired level of anesthetic. If the patient is in the age gap between 60+ then there will be a much more controlled dosages applied, because their already suppressed breathing due to age may be severely hindered and cause problems if too much is given too quickly.

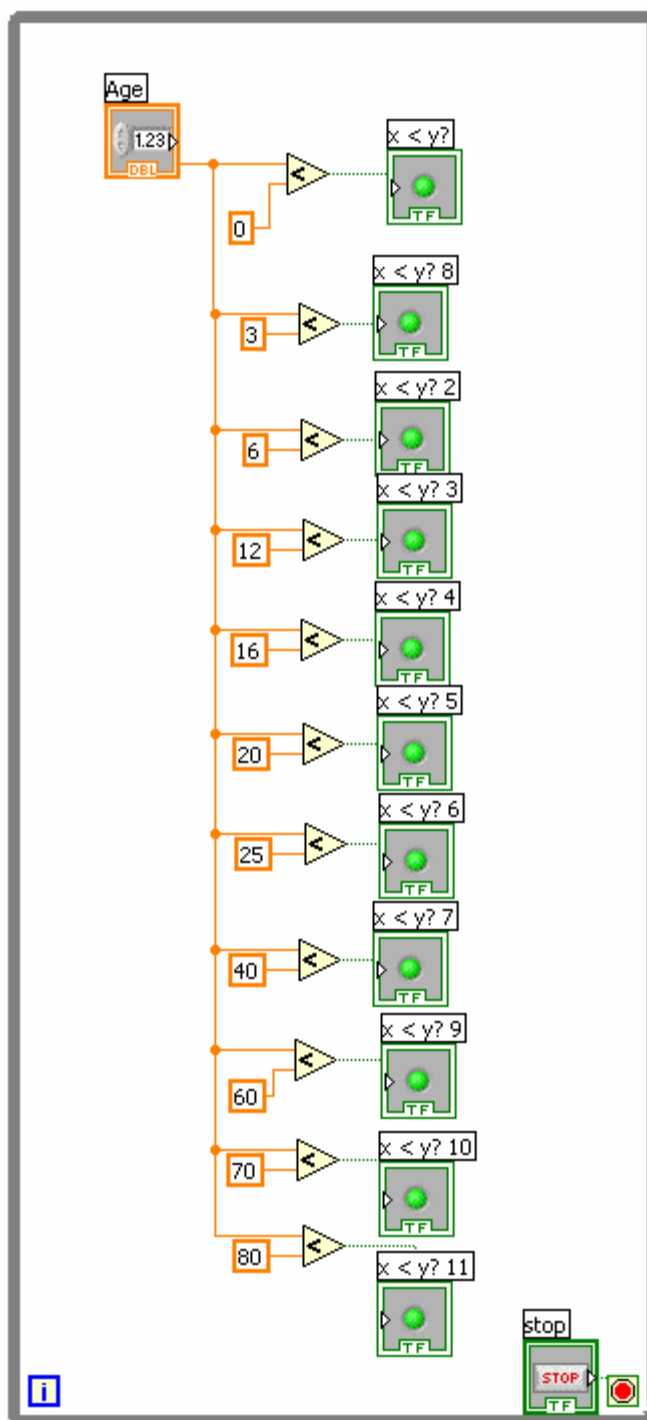


Figure 27: Age calculator for dosage.

The patient's weight will be placed in a range that will be used to calculate the dosage change. If the patient fell into the 150-170 pounds range, it would be considered average and there would be no effect on the dosage by weight. If the patient was between 170-200 pounds then the number would be turned into a percent over 100 and multiplied by the dosage to obtain a



quantity that it must be increased by to compensate for the over weight factor. If the patient were below average weight, the number would become a percentage under 100 and would be multiplied by the dosage and then subtracted from the normal dosage and then the difference would be added. If this number is too dramatic then the number can be altered by a percentage that would be applicable. This is just how the weight will be correlated to the correct dosage.

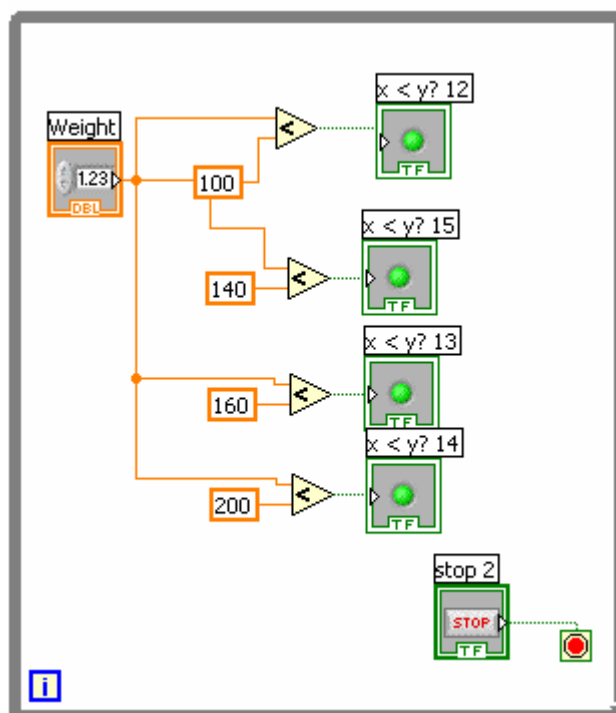


Figure 28: Weight calculations using LabVIEW™.

The patient's sex will have a slight effect on the dosages applied to the patient as well. If the patient is a male then it is more likely that they will have a higher metabolism and will be able to process the anesthetic faster and there will be a stronger effect on the patient faster. Also a male usually has a larger body structure which means that it may take longer for the medication to take full affect. Each of these factors will be incorporated into the dosage changes dependent on more research.

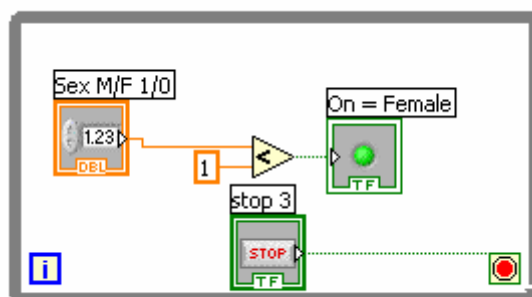


Figure 29: Sex calculation using LabVIEW™.



If the patient is in a high level of physical condition, then their metabolism will be faster and their body may have a lower state of rest than the average person. This means that they will usually need a smaller dosage of anesthetics due to the fact that there is less fat and more sensitive effectors in the body to receive the drugs. The patient will be judged by a list of exercise traits and exactly how many hours of exercise is performed a week and then the patient will fit into a category between one and one-hundred that will give a consistent diagnostic pattern. This will then affect the dosage applied on a small scale due to the fact that patients could be lying, and the effect of a more physically fit patient only has a moderate affect on the dosage needs. In figure 30 the LabVIEW™ program will separate the patients below a certain weight and then pass the integer to a summer which will allow the dosage to be adjusted using the percent. This block diagram will be very similar for each function that will be calculated. The constants will be the only part that really changes.

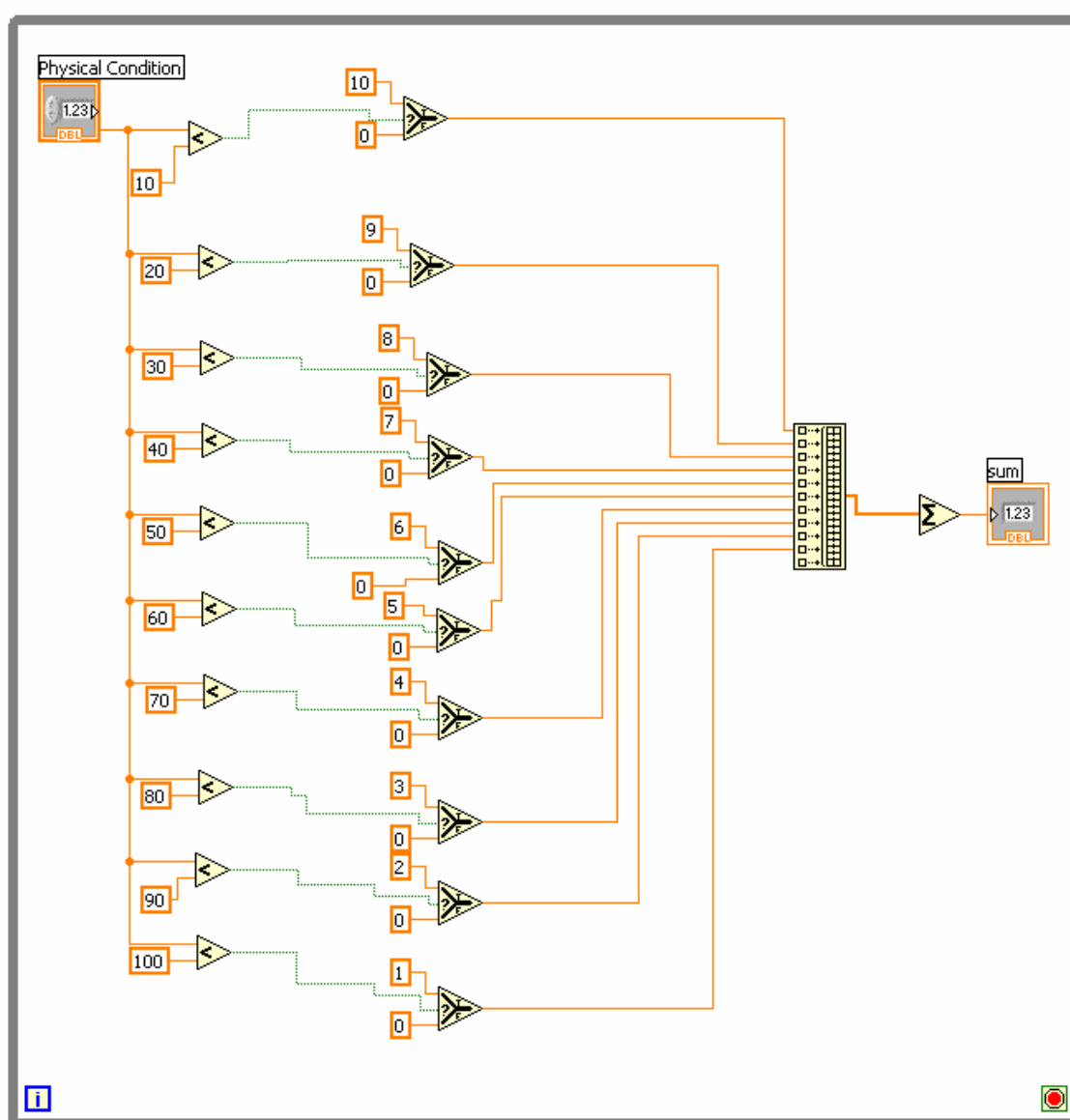


Figure 30: Physical condition dosage calculation using LabVIEW™.



If the patient has a normal medication that is a part of their normal routine or has a intake of over the counter drugs then there will be a list that the patient can pick a category that they fall in to meet a gap in the one to one-hundred scale. This numerical value will then be applied to the dosage and will have a relatively moderate affect on the actual dosage. The more medicine the patient uses regularly combined with the type of medicine will make the patient have a higher dosage to avoid the fact that they are more immune then average. This block diagram will be similar to the one for physical condition.

Recreational drug use must be considered as well. If the patient is an extreme recreational drug user first they must go through blood checks to make sure none in there system will affect the anesthetics. Next the type of drugs used will fit into a category that will be applied to a number that will allow for the correct adjustments in the dosages applied. If the patient is a avid pain killer user, then the applied dosage will have to be bumped up quite a bit to make sure that the patient will not feel pain while under anesthetic. If this is not done the procedure could make the patient endure quite a bit of pain with out a way of telling anyone due to the suppressing anesthetics. Depending on the drugs used a category from one to one-hundred will be selected that best fits the patient, the more affect the drug has on diminishing the effects of anesthetics the higher the dosage will be applied. This LabVIEW™ set up will also be similar to the one used for physical condition.

Alcohol use is usually over looked when people are discussing recreational drugs so its own category was created. If dependent on how much alcohol the patient has consumed there will be a smaller dosage of anesthetic applied per dose because anesthetics can put a strain on the organs in the body including the kidneys. If the kidneys are already at a weakened state then a smaller dosage must be applied to save them further damage. This block diagram will follow the same format as the one for physical condition.

If a patient has gone through prior procedures they may have built up a tolerance to the drugs used in the process of anesthetic and the doctor can change the prior resistance in categories that fit into a list provided to them. If the patient has one prior occasion where anesthetic was used then the value will be one. The dosages will be increased to compensate for the fact that the body may have become more used to drugs then others. The calculations for this will be similar to the ones for the physical condition as well.

If the patient is in a state of disease then their body maybe at a weakened state and the dosages must be decreased as to not cause more problems with the sicknesses that the patient is encountering. Sicknesses will be labeled into correct number format between one and one-hundred to account for the level of change that needs to occur in the dosage. The sicker the patient the smaller the dosages will be at increments. This will have a block diagram that will be based off of the one for physical condition but each value will represent a disease and the constants will be written into a chart to make it easy on the user.



2.2.2.5 Material Requirements

2.2.2.5.1 Case

The casing structure that will be used to house the monitor and the electrical components should be a durable, protective and light material. The best choice is going to be a polymer based purely on its mechanical strength and its light weight. The polymer should be soft enough to absorb some of the force if the device is dropped or tipped over. Acrylonitrile Butadiene Styrene (ABS) plastic would be an appropriate choice because it has very good shock absorbing properties, can be molded to fit any shape needed, and is therefore a perfect candidate for enclosure materials. This exterior covering should be large enough to encompass all the materials necessary to run the monitor, while maintaining a small size as to not get in the way of other devices in the room. We will have to have the internal components spaced such that the weight is evenly distributed front to rear so as to prevent the device from tipping over if it is not mounted on a stand or cabinet. The dimensions of the case will be such that it is not too narrow in either of the base dimensions so it can sit sturdily on a hard flat surface. The front panel of the case should be easy to clean since there are a variety of fluids that could potentially spill onto the device. This means that the screen and buttons will be mounted behind a thin plastic film creating a flat seamless surface that can easily be wiped down. There will have to be good ventilation that will allow for the monitor to run without over heating. The interior of the case should be sized so that the electronics components should take up as much space as possible within the case without sacrificing the functionality of any of the circuits. Each circuit involved should be properly grounded and checked for leakage current before the case is sealed. Figure X is an example of a case that would be able to support the monitoring system.



Figure 31: Example case for the monitor

This specific box is made of high impact polystyrene. This case is approximately 16"Wx9.5"Hx3"D. This box supports a mother board and enough room that the monitor could be inserted into the front panel with ease and there is enough space to fit the necessary internal components. Our case needs to have an opening that can fit the LCD monitor, and an area to the side of the monitor sufficiently large enough for the buttons to be mounted without becoming too cluttered. The rear of the case needs vents on one side to allow fresh air in, and an area to mount the fan on the opposite side to draw the air out. If these vents are not present in the purchased case they can be cut in to allow sufficient airflow. Figures 32 and 33 are schematics of the front and rear of the case.

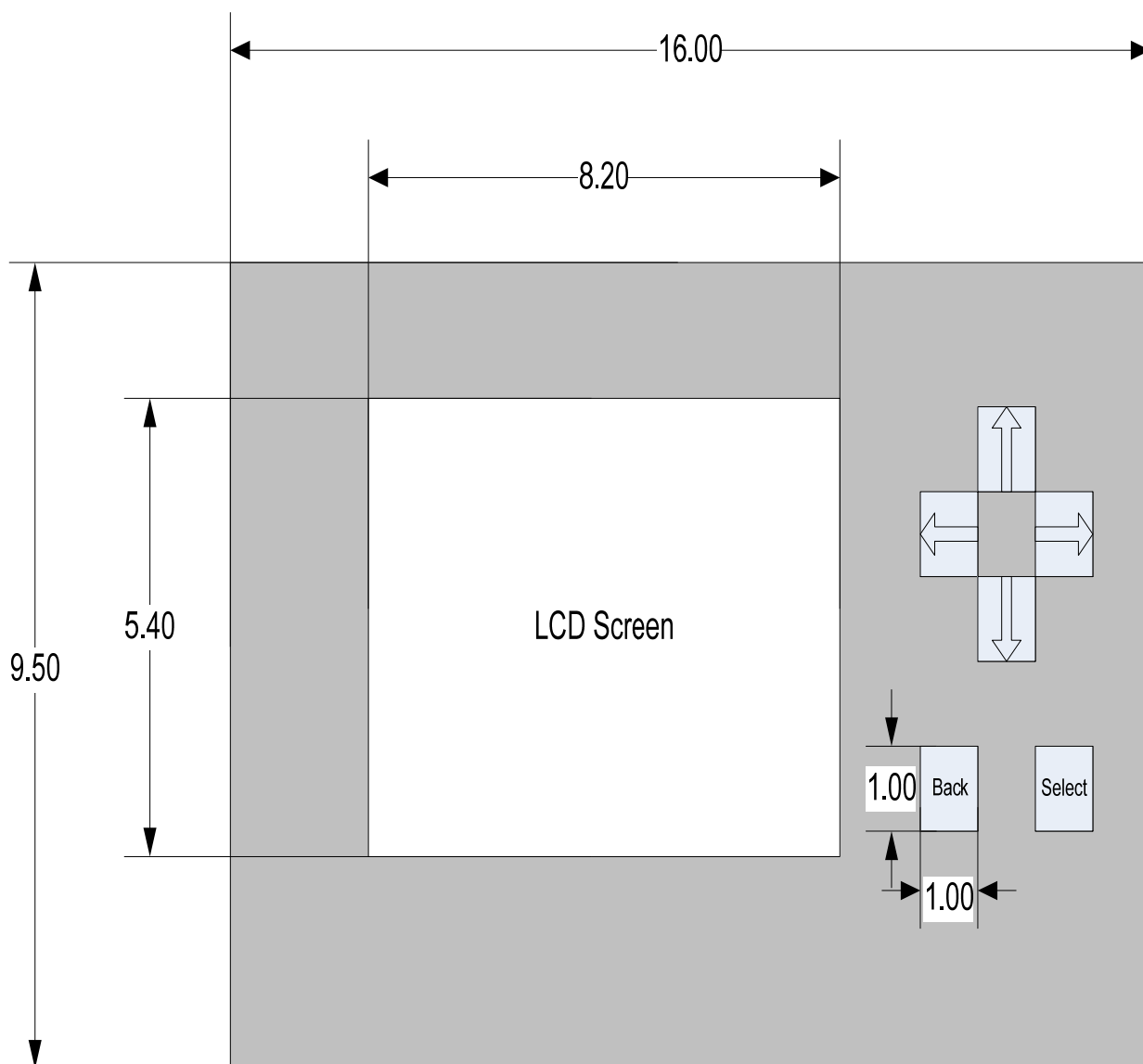


Figure 32: *Front of the case*

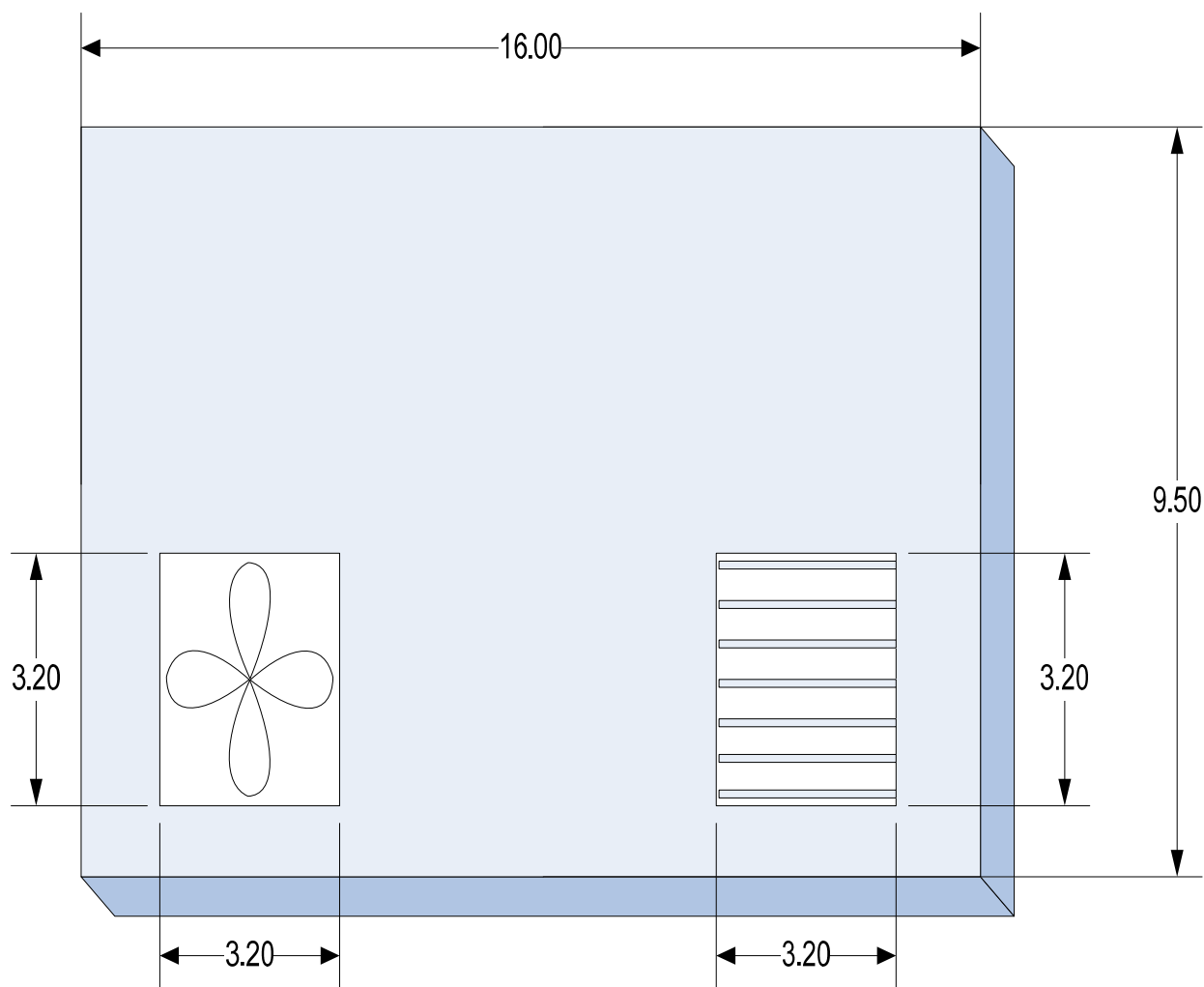


Figure 33: *Rear of the case*

1.2.3.1 Interface Screen

The flat screen panel being used for the monitoring system should be large enough to have a clear display of the visual graphics that need to be displayed for quick reference by the anesthesiologist. Figure 34 shows an LCD monitor that would fit the requirements for the project perfectly. This model has visual enhancements available on the frame of the screen. This screen is clear and will allow for a good picture quality for clear numerical values and clear graphs. The eight 10.4 inch display will be sufficiently large enough display all the graphs that will be needed for the anesthesia monitor. The informational specifications of the LCD screen displayed in figure 34 are described in detail in figures 35 and 36, including weight, resolution, and dimensions.



Figure 34: 10.4" LCD monitor

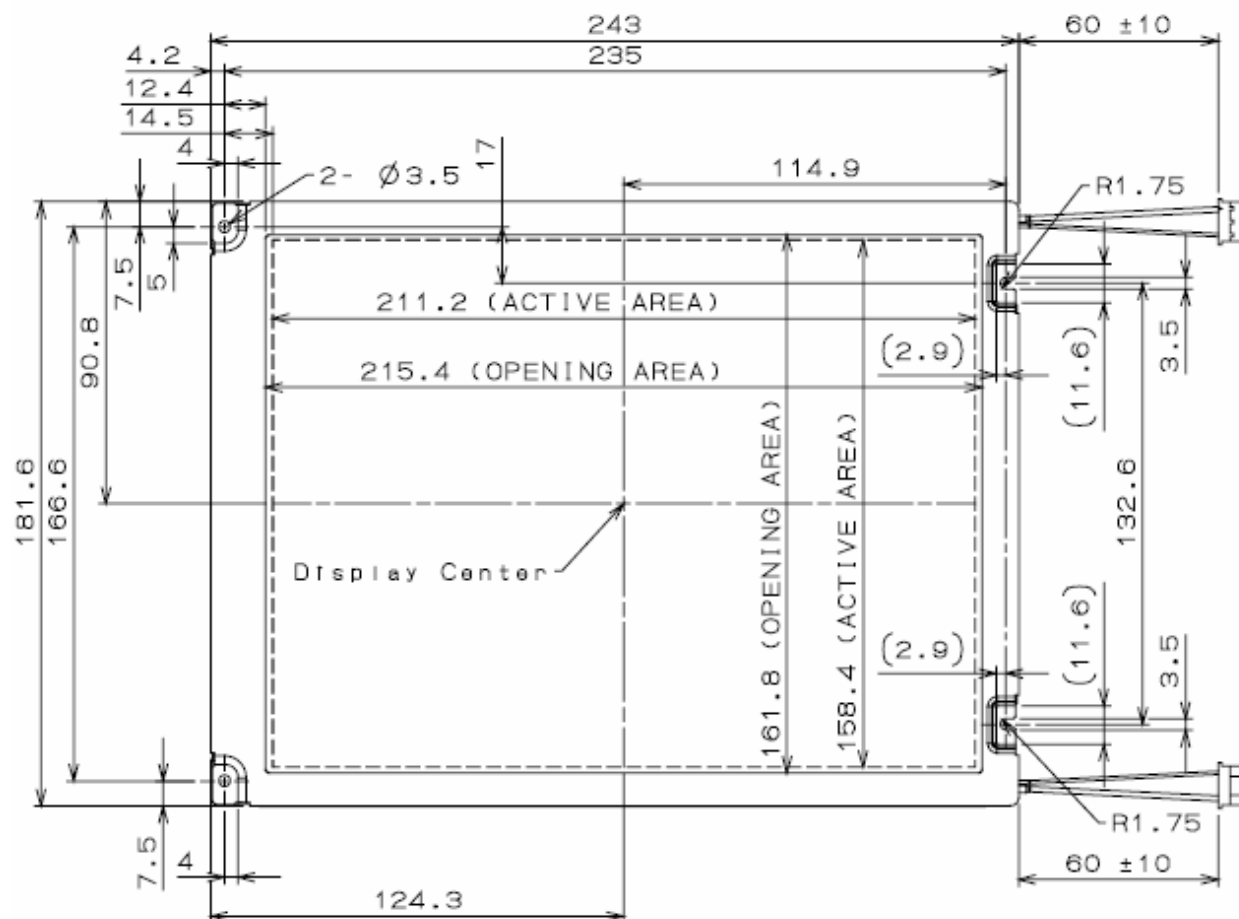


Figure 35: Block diagram of LCD display



ITEM	SPECIFICATION
Display Area (mm)	211.2 × 158.4 (10.39-inch diagonal)
Number of Dots	800 × 3 (H) × 600 (V)
Pixel Pitch (mm)	0.264 (H) × 0.264 (V)
Color Pixel Arrangement	RGB vertical stripe
Display Mode	Normally white TN
Number of Color	260 K(6 bit/color), 16.7 M(8 bit/color)
Brightness (cd/m ²)	400
Wide Viewing Angle Technology	Optical Compensation Film
Viewing Angle (CR ≥ 10)	-70~70° (H) -60~50° (V)
Surface Treatment	Anti-glare and hard-coating 3H
Electrical Interface	LVDS(6 bit/8 bit)
Optimum Viewing Angle (Contrast ratio)	6 o'clock
Module Size (mm)	243.0 (W) × 181.6 (H) × 12.2 (D)
Module Mass (g)	570
Backlight Unit	CCFL, 2-tubes, edge-light, replaceable

Figure 36: Specifications for the LCD screen

2.2.2.6 Key Pad

In order to control the LCD screen and the operation of the LabVIEW™ program we must install buttons on the exterior of the case. These buttons must be easily operated, and clearly labeled to avoid any confusion as to their function. We will use a total of six buttons for our device. Four of the buttons will be arranged in a cross pattern and will function as up/down and left/right arrows. These will be used to navigate the menus and options of our LabVIEW™ program. The other two buttons will be used as an “OK” button and a “Cancel/Back” button. These buttons will confirm selections and go back in menus in order to change previously made selections. The button layout is described in Figure 37.

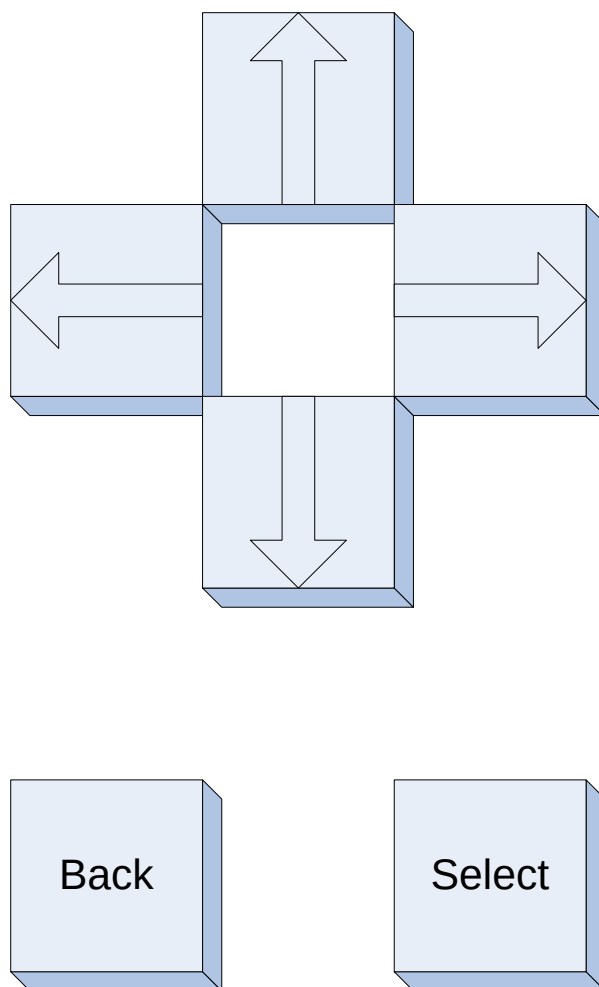


Figure 37: Possible button layout

For the specific buttons we will be using a push-to-make SPST (single pole single throw) momentary push button switch. A push-to-make switch is normally in the off position, and when pushed they form the connection. These particular switches have a single pole which means that when pushed they serve one function, and since they are momentary they will return to the off position once released. Figure 38 is a circuit symbol and example of a push to make switch.



Figure 38: Circuit symbol and example of a push-to-make switch

The specific switches we will use will need to be mounted flush to the exterior of the case. They will be surface mount tactile switches with approximate dimensions of 6mm x 6mm. After the button is mounted, a sheet with the button functions will be placed over the buttons to create a flat button panel. The size of the buttons is large enough to be pressed easily, but small



enough to not get in the way of operations of the device. Figure 39 is an example of a surface mount switch that will be used.

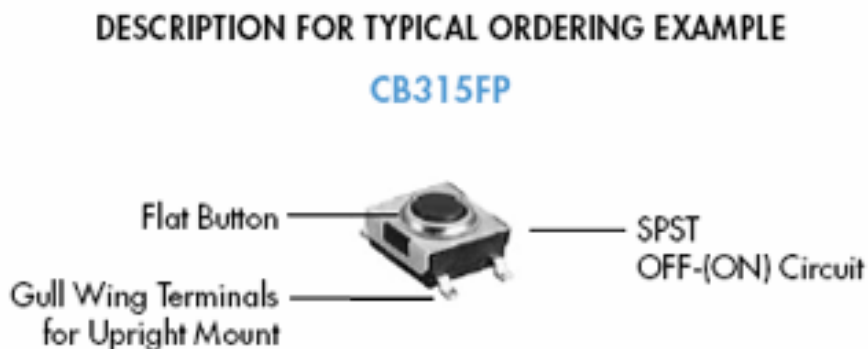


Figure 39: Surface mount tactile switch

TYPICAL SWITCH DIMENSIONS

Single Pole • Single Throw

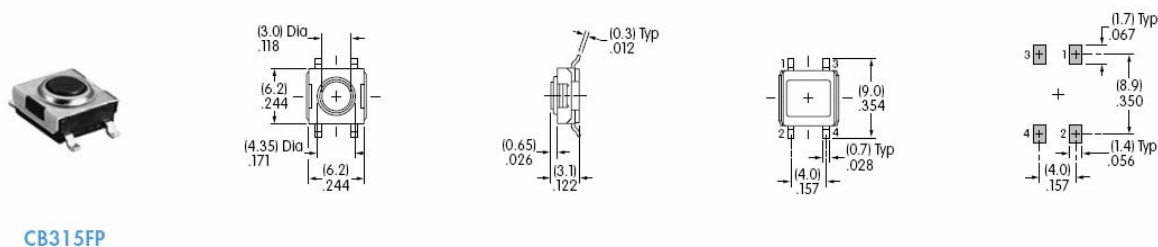


Figure 40: Switch dimensions

These switches will be mounted on the external front panel of the case, and connected internally via wires to the printed circuit board containing the LabVIEW™ program.

2.2.2.7 Cooling Fan

Most computer components and devices are rated to work properly at a temperature less than approximately 176°F. The power source, monitor, and internal circuitry will create heat within the case. To avoid any complications or failure as a result of the increased heat, cooling fans will have to be installed in the case. Figure 41 is an example of a fan that will be installed.



Figure 41: Cooling fan

This particular fan is small enough to fit into the space on the side of the case. The noise level created by a fan is comparable to a human whisper, which is negligible in an operating room environment. The case itself will be in the area of 0.125 to 0.33 ft³. This fan moves air at a rate of 23.8-41.6 cubic feet per minute, which means the air in the case will be replaced 72-332 times per minute allowing for sufficient cooling. The following is a list of specifications for the fan:

- **Fan Size:** 80 x 80 x 25mm
- **Bearing Type:** Double Ball Bearing System
- **Air Flow:** 23.8 - 41.6 CFM
- **Speed:** 1950 - 3400 RPM
- **Noise Level:** 25.3 - 37.5 dBA
- **Rated Voltage:** 12V DC

One fan will be installed in the device. The fan will be installed on the rear of the case in order to draw the air outward. This will draw the heated air out of the case and fresh, room temperature air will be allowed to enter through vents on the opposite side of the rear of the case. See section 2.2.5.1 for schematics of the case.

2.2.2.8 Power Source

The monitor will be plugged directly into a standard 120V commercial outlet. The power supply used will have a toggle On/Off switch to power down the whole system. Figure 42 is the plug inlet that will be mounted to the rear of the case.



Figure 42: Double-Fused Three Function Power Entry Module

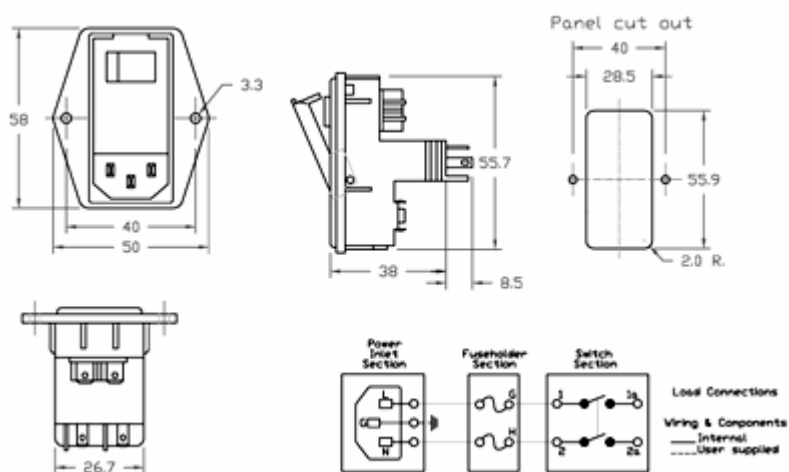


Figure 43: Schematic of Power Supply

**Specifications** (Note: dimensions in mm)

Part Number: 83110022	Fuse: yes
Int'l Current Rating: 10A	Number of Fuses: 2
Int'l Voltage Rating: 250VAC	Fuse Size: ¼ x 1¼"/5x20mm
N.A. Current Rating: 6A	Voltage Selector: no
N.A. Voltage Rating : 250VAC	Voltage Selector Settings:
Temperature Rating: 65°C	Circuit Breaker: no
Flammability Rating: UL 94V-0	Filter: no
Operating Frequency:	Leak Current Value:
Class: I	Filtering Bandwidth :
Quick Disconnects: 9/4.8mm	Mounting Style: Screw Mount
Solder Tabs: 9	Panel Thickness:
Terminal Material: Nickel-plated brass	General Material: Thermoplastic
Power Inlet: yes	Color: Black
Access Outlet: no	Medical: yes
Sheet Style: C14	CE Marking: no
Switch: yes	
APPROVALS: VDE UR CSA	

REMARKS: Fuses and fuse carriers not provided. Doublefused for medical applications.

Last Modification: 07/21/06 • 16:37:46 • dford
notice

***Specifications subject to change without**

Figure 44: *Specifications for Power Supply*

In case of any damage to the cord, we will use a replaceable cord that is the same style as those used to power a personal computer. Figure 45 is the power cord that will be used to power up the device.



Figure 45: *Power Cord*

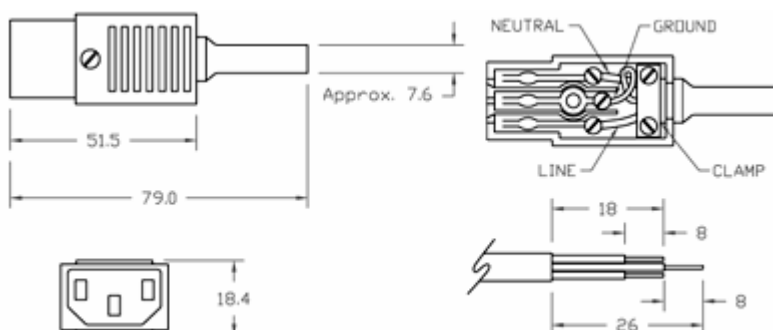


Figure 46: Power Cord Schematic

Specifications (Note: dimensions in mm)

Part Number: 83011152

Int'l Current Rating: 10A

Int'l Voltage Rating: 250VAC

N.A. Current Rating: 10A

N.A. Voltage Rating : 250VAC

Temperature Rating: -40°C to 70°C

Flammability Rating: UL 94V-0

Class: I

Quick Disconnects: 0

APPROVALS: CSA VDE IMQ SEMKO UR

Solder Tabs: 0

Terminal Material: Brass

Sheet Style: C13

Mounting Style: Cable Mount

Panel Thickness:

General Material: Thermoplastic

Color: Black

CE Marking: yes

REMARKS:

Last Modification: 02/20/06 • 10:08:27 • jcaligi

***Specifications subject to change without notice**

Figure 47: Power Cord Specification.

2.2.2.9 Electric Circuits

2.2.2.9.1 Low-Pass Filter

The Expert anesthesiology monitoring device will require a variety of electrical components. The most important components will be the active filters that will provide voltage amplification and signal isolation. To acquire the most accurate data, a second order filter will be used to obtain close information to ideal characteristics which creates a more effective filter. There are two general types of active filters; a low-pass and a high-pass. The purpose of the low-pass filter is to effectively attenuate all of the undesirable high frequency noises. Figure 48 is an example of a second order low-pass filter. The cutoff frequency is determined with this



equation: $f_{OL} = \frac{1}{2\pi R_1 C_1}$. The distinguishing features that make it second order filter is the second set of resistor/capacitor combination connected to the positive terminal. The low-pass filter is shown in figure 49 through the graphical interpretation of using the Bode plot method.

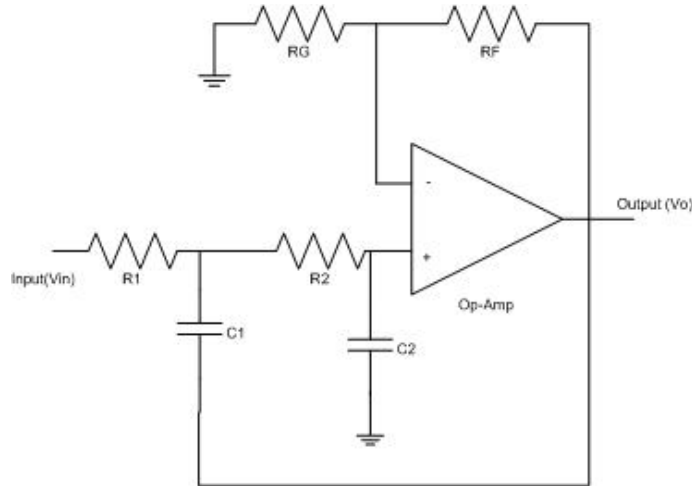


Figure 48: The circuit schematic of a Low-pass filter

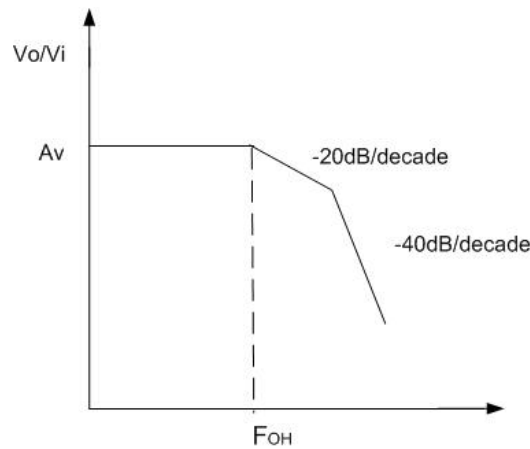


Figure 49: Low-pass Bode Plot

2.2.2.9.2 High-pass Filter

The high-pass filter is created with a similar setup to the low-pass filter. However, the C1, C2 and R1, R2 positions are switched. Opposed to the low-pass filter this setup attenuates low frequencies reducing any noise with a frequency below the cutoff frequency to be eliminated. Figure 50 displays the High-pass filter. The cutoff frequency is determined in the same way as the low-pass. The equation relating the filter with the circuit is $f_{OH} = \frac{1}{2\pi R_1 C_1}$.



The cutoff equations can be used to adjust the filtering parameters to accommodate the individual vital signals for the expert anesthesiology monitoring device. The graphical display of a high-pass filter is shown in figure 51.

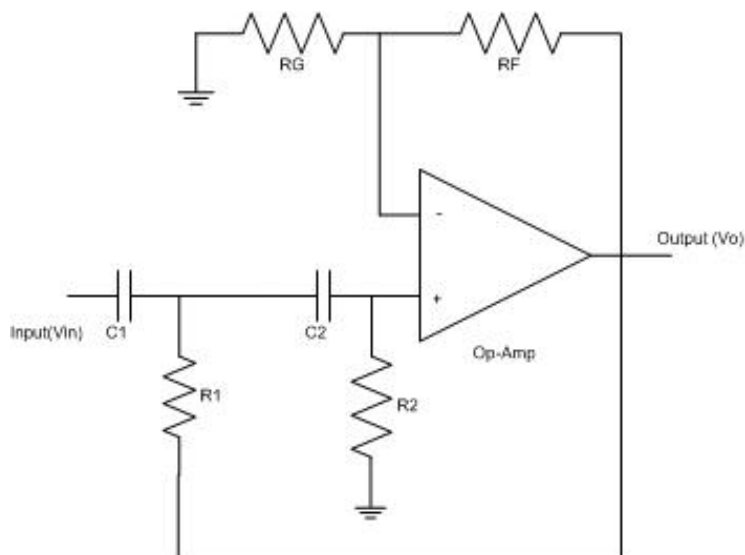


Figure 50: The circuit schematic of a High-pass filter

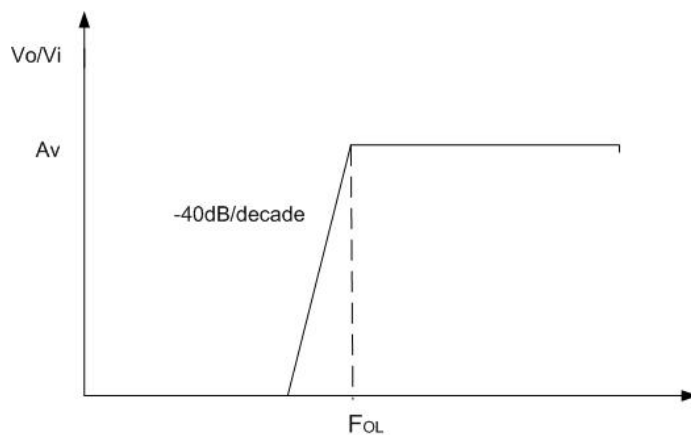


Figure 51: High-pass Bode Plot

These filters also provide an amplifying effect creating clearer output and will allow for easy analysis. The amplification is influenced by ratio between resistors R_G and R_F . The equation relating these resistors is $A_v = 1 + \frac{R_F}{R_G}$. Depending on the type of signal the specific circuit is dealing a different combination of resistors will be used for applying the correct amplification.



2.2.2.9.3 Band-pass Filter

These filters can be combined into circuits in series to produce filters effect that are know in industry as a band-pass filter and a stop band filter. Each is used for it's inherit filtering characteristics. The band-pass filter is the combination of a high-pass and low-pass filter producing a filter that an effect of an inverted parabola. Any frequencies exceeding the upper and lower cutoff frequencies will be attenuated eliminating any back ground noise. The band-stop filter used when there is a need for eliminated a noise spike. An example of a common noise spike present in most vital signals is the power line noise.

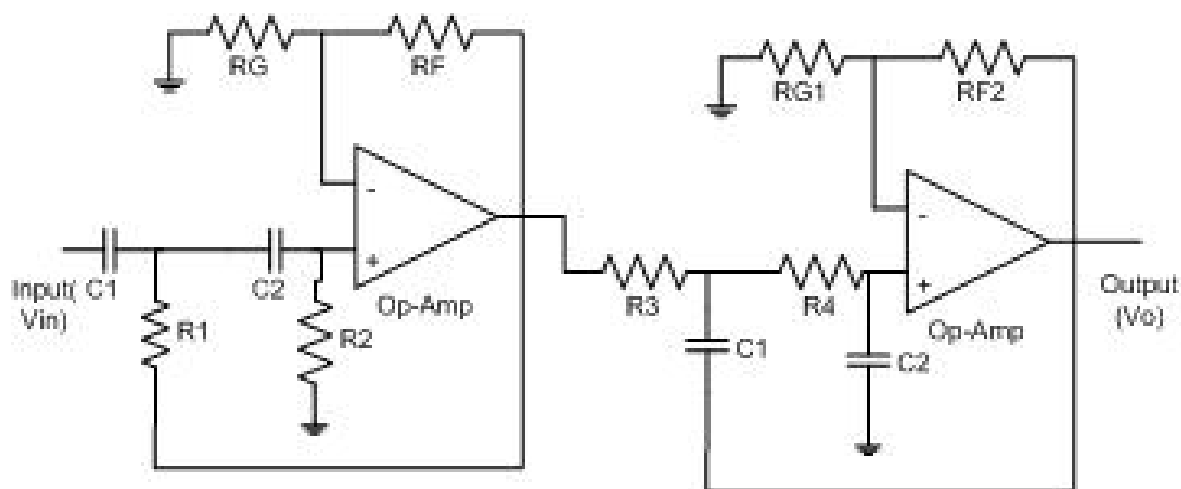


Figure 52: The circuit schematic of a Band-pass filter

Determining the specific values of each circuit element will determine using preexisting information about the electroencephalogram, electrocardiogram, pulse oximeter and Blood pressure. The current filtering parameters for the EEG and ECG are displayed in Table 9.

	EEG Signal		ECG Signal	
EEG waves	f_{OH}	f_{OL}	f_{OH}	f_{OL}
Alpha	0.0833Hz	0.125Hz	0.05Hz	40/100/150Hz
Beta	0.0333Hz	0.077Hz		
Detla	0.143Hz	0.25Hz		
Theta				

Table 9: EEG and ECG filtering parameters

2.2.2.9.4 Leakage Current

Another electrical concern is the current leakage. Current leakage is described as the current that flows from the internal device through the grounding conductor and then into the hospital ground. Leakage current could shock nearby individuals near the monitoring device. This would severely hinder the surgical procedure and may have fatal results for the individual who received the shock. Leakage current the in range of 3mA can easily create shock and possible pain for the individual making contact. Current meeting or exceeding 8mA causes



cardiac arrhythmia and if the current is great enough fatalities will result. To ensure that leakage current does not occur, proper grounding and insulation should be implemented into the design. Designers commonly use protective earth grounds connected to the case to maximize the device's safety. This is accomplished by connecting a leakage current tester to a ground then testing the external metal components of the device. If the components carry amperage above a certain safety level, the device is leaking current. Also, the power cord must be tested for leakage. This is done by connecting the device directly to the leakage current detector. If when the cord is moved the milliamp current reading fluctuates, the cord is leaking current.

In order to prevent leakage current and prevent it once it is found, the electric components must be properly grounded. The AC cord and power source has a grounding wire built into it, and in order to ground the device all the components must be connected in some way to this ground.

2.2.2.10 Real Time processing

As requested by our sponsor the anesthesiology monitoring device will display real time processing allowing immediate data analysis because the output is concurrently generated with the collection of the initial data. If the device did not process in real time a complete data set would have to be collected before any processing took place. The monitoring device would provide no advantage if the analysis only took place after each surgery. Real time processing is the most immediate data processing means, however there is still a small delay, approximately 10 milliseconds, but a delay at such a small scale will not hinder the outcome.

Real-time applications input a sample, perform the algorithm, and output a sample, over and over. These repeated steps are often referred to loops within the program. It allows the same process to occur over a period of time until the loop expires. Another method is organizing them by groups of samples, perform the algorithm, and output a group of samples. The best way to accomplish real time processing is to process in groups. The most efficient way is to implement circular buffering. Circular buffering is a method of storing data in memory and continually update as new data is acquired.

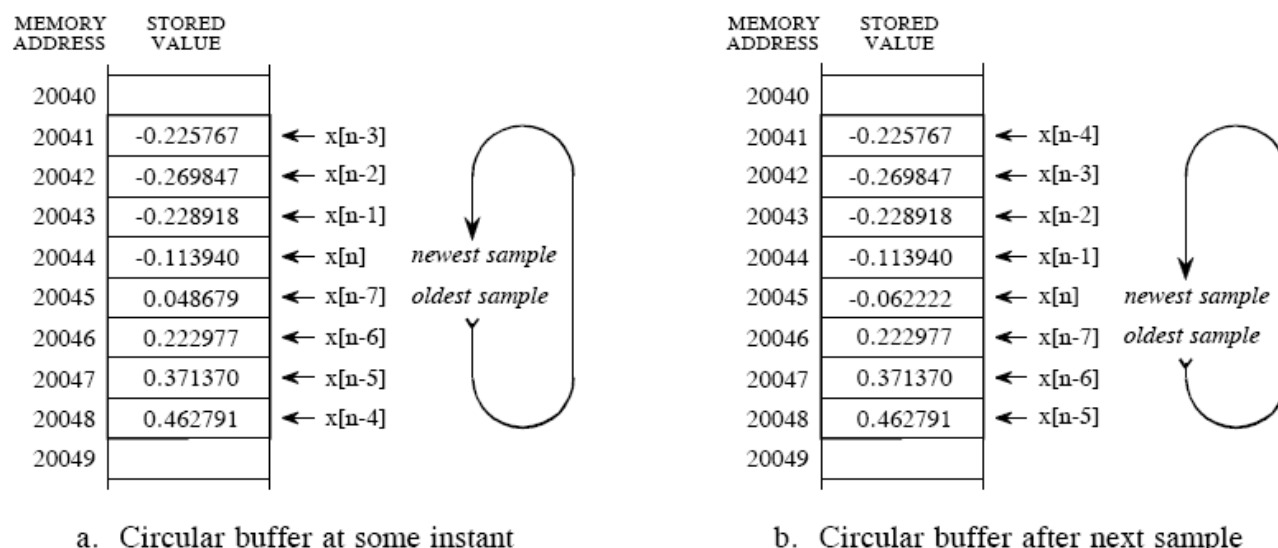


Figure 53: Circular buffer operation. This shows an example of how a circular buffer will look at one instant (a) and the following instant (b).

2.2.2.11 Digital Signal Processing

Generally, Digital Signal Processing, DSP, is the study of signals in a digital representation and the processing methods of these signals according to Wikipedia. For this particular design project we are solely concerned with the processing methods because the analog signaling processing is taken care of by the BIS and GE devices. There is still a debate on whether or not an alternative to the BIS monitor should be required. If an optional EEG transducer needs to be implemented into the anesthesiology device then analog signal processing will need to be considered.

2.2.2.11.1 Fixed point vs. Floating point systems

Digital signal processing can be divided into two methodologies, fixed point and floating point. These terminologies refer to the format used to store and manipulate data within each device. Fixed point DSP represents each number with a minimum of 16 bits, although a different length can be used. Floating point DSP uses a minimum of 32 bits to store each value, which provides a maximum of 2^{32} patterns. The key feature of floating point notation is that the represented numbers are not uniformly spaced. This translates into better precision, higher dynamic range and shorter development cycle. These processing advantages are contributed to its internal architecture. The differences between the two processing methods are significant enough to require unique implementation methods such as algorithm implementation. Floating point will be used in the device for the reduced development, but the precision and dynamic range also makes it advantageous. Figure 54 shows tradeoffs between the two system types.

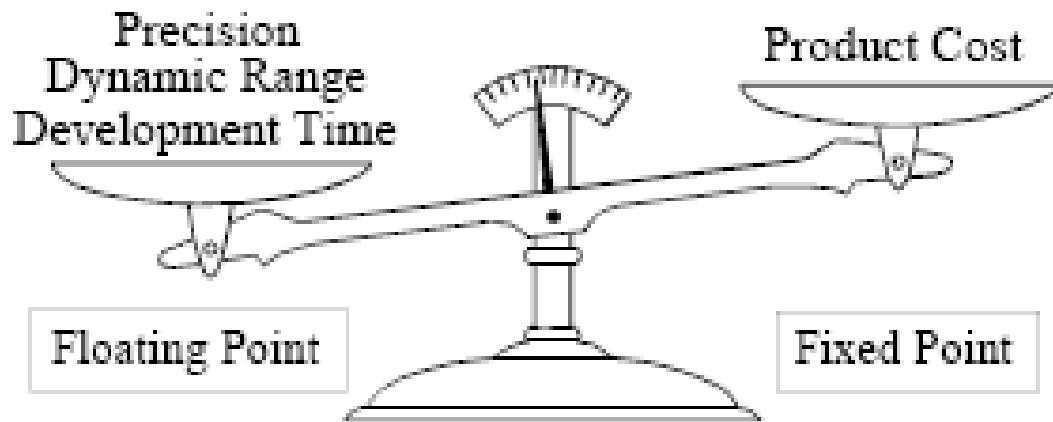


Figure 54: Floating and Fixed point trade offs

If the optional EEG transducer is implemented another advantage of using floating point systems is the signal to noise ratio, SNR(dB). The SNR is calculated using the equation: $SNR(dB) = 20 \log(\frac{A_{signal}}{A_{noise}})$. This background noise is introduced to the signal during the analog-to-digital conversion because of the quantization of the signal. For a fixed point system the ratio is worse compared to a floating point system because their gaps between adjacent numbers are much larger. The two equations for fixed and floating SNR are: fixed-SNR=6.02n and floating-SNR=6.02(n-m). Where n is the n-bit integer, fixed or floating depending on the system and m are the bits found in the exponent.

Noise, found in signals, is represented by the signals' standard deviation. The standard deviation is about one third of the gap size between bits. Meaning the signal to noise ratio for storing a floating point number is 30 million to one opposed to fixed point is 10 thousand to one. This reveals that floating point has about 30 thousand times less quantization noise than fixed point. Having any noise within a signal becomes a problem when the signal is amplified. The signal to noise ratio gets progressively worse as more elements are added that further lower the ratio, such as introducing a filter. When a filter is added the signal to noise ratio is lowered from 10k to 1 to 20 to 1 making signal reconstruction impossible.

In addition to increased signal to noise ratios, floating point systems are easier to develop application algorithms. Most DSP techniques are based on repeated multiplications and additions. When dealing with fixed point systems programmers are required to constantly understand the amplitude and how the quantization errors are accumulating, which isn't required by programmers using floating point systems.



2.2.2.11.2 Programming languages

DSP processors are mainly programmed in Assembly or C. This device will be programmed in LabVIEW™ and then compiled into C and uploaded onto the microprocessor. Using C and a microprocessor allows programming without a full understanding of the microprocessor's architecture. The compiler assigns each of the variables with a home location which will keep track of their values. We will use C for the flexibility and fast development. Later versions will be converted to Assembly to increase performance. Figure 55 shows the trade offs between the two programming options.

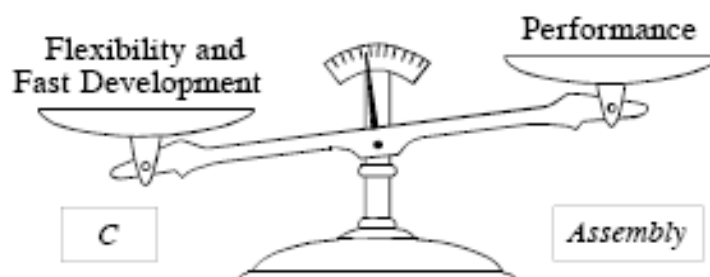


Figure 55: Programming trade-offs.

Due to the limited time and experience programming in C will provide the most flexibility and minimal development without sacrificing the final product. To optimize the processing, loops will be implemented into the program allowing parallel processing.

```
001      i12 = _y;                                /* i12 points to beginning of y[ ] */
002      i4 = _x;                                  /* i4 points to beginning of x[ ] */
003
004      f2 = dm(i4,m6), f4 = pm(i12,m14)           /* prime the registers */
005      f8 = f2*f4, f2 = dm(i4,m6), f4 = pm(i12,m14);
006
007      lcntr = 18, do (pc,1) until lce;           /* highly efficient main loop */
008      f12 = f8 + f12, f8 = f2*f4, f2 = dm(i4,m6), f4 = pm(k12,m14);
009
010      f12 = f8 + f12, f8 = f2*f4;                /* complete the last loop */
011      f12 = f8 + f12;
012
013      dm(_result) = f12;                        /* store the result in memory */
```

Figure 56: Example Loop code.

Figure 56 explains the general idea of how loops will be incorporated into processing and allows continuous computations. Line eight is the only line in the loop. However this line contains a set of instructions to optimize the computations. Line four and five



are considered the priming code because they allow for line eight to exist and function properly. The LabVIEW™ program will consist of a similar structure that allows multiple operations to be carried out.

2.2.2.12 Testing

2.2.2.12.1 LabVIEW™ Testing

The testing of LabVIEW™ will involve a break down of the program into smaller portions to make sure that all the parts work independently before combining them into one program. The program will mostly be broken down into each individual component. After each of the signals are working independently and the errors are deciphered and fixed, the program will be consolidated into and will be run through one Data Acquisition or DAQ assistant. This is where most of the problems in the program should be experienced. When combining multiple working signals into one, there is an error rate that has to be accounted for. The chance that multiple programs can be combined without interference is implausible.

The testing without the circuits attached can be done with programmer installed data. Instead of using the circuits to input the data from the patient, signals can be simulated and applied to the program to make sure that the program can process and display the data correctly without error. At this point the filters can be tweaked and the noise will be separated from the signal and can be filtered out. This will allow for the most precise measurements. Knowing the signal that should be outputted will allow for a proper diagnosis of noise and error in the outputted signal and graph.

2.2.2.12.2 Circuit Testing

Testing the electrical hardware will be done in two ways. First using PSpice the circuit build and simulated with the calculated resistive and capacitive components. Once the board has gone through extensive virtual trouble shooting it will be translated into electronic hardware. This hardware will be required to undergo additional tests to check whether or not there were errors incurred during fabrication and soldering of the components.

Each of the signals will require specialized components to meet their amplification and filtering needs. First the circuitry will be verified by testing the amplification and filtering. Given that each signal requires a unique set of filtering and amplifying parameters the circuitry components will be customized set their requirements.

For example the EEG amplitudes and frequency components vary from 10-100 μV and from 0.5-30Hz respectively and within these general parameters there are sub parameters correlating to the different periodicity's which compose the EEG signal. Each of these periodicities is characterized by a more specific frequency and amplitude as well as the conditions which they are most apparent. The filtering of this design will be completed solely in analog domain.



The approach to verify the functionality of the circuit will be to connect a function generator to the input of the circuit board and to channel 1 of an oscilloscope and connect channel two of the oscilloscope to the output. This will provide an easy way to compare the inputted signal to the outputted signal. The input signal will be attenuated by the same scale that that output signal is amplified by which will reproduce the un-attenuated signal. To manually test the filtering of the circuit board the frequency of the created signal will be move around each cutoff frequency. As the frequency exceeds a cutoff frequency the signals should be attenuated to about zero. Figure 57 displays a general setup for a function generator and oscilloscope.

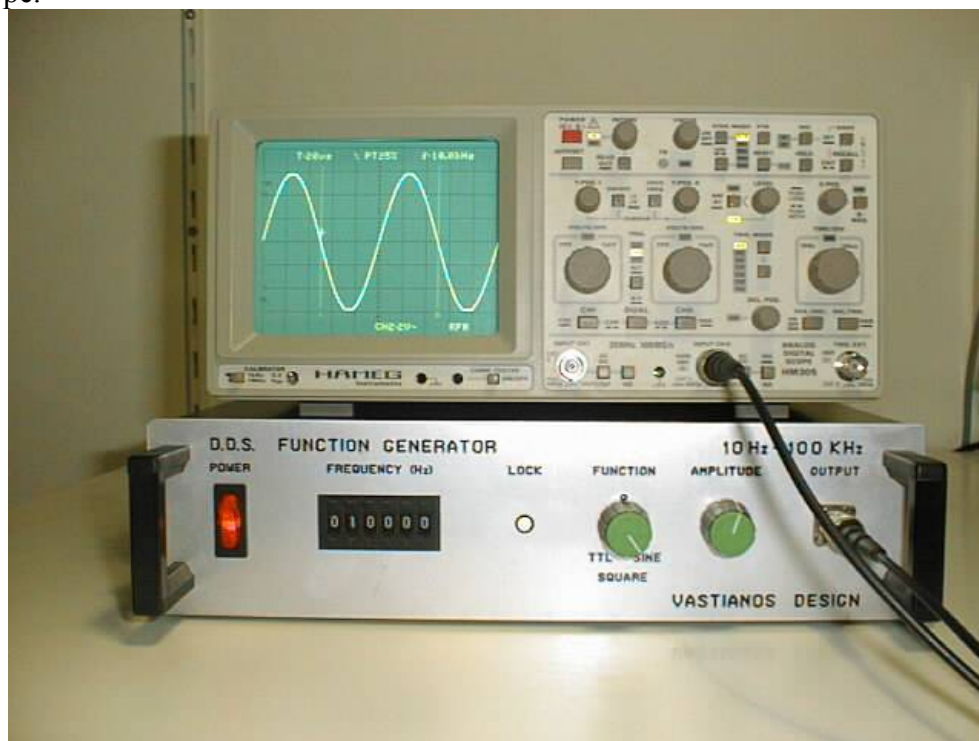


Figure 57: function generator and oscilloscope setup

2.2.2.12.3 Total Testing

The total testing of the LabVIEW™ program and the circuits once they are all set up will involve using Biopac equipment for the ECG and blood pressure. For the other signals, sensors will have to be bought, tested and applied to the corresponding signal before combination. There will be sensors set up and attached to the LabVIEW™ program where the sensors will be attached to a patient, or a test subject. The program will be run while the test subject is in a physically active state, or has just completed physically straining activity, which should allow a spike in the level of consciousness monitor. Then at a separate time the patient will be totally relaxed or even asleep while the next test is taken. If the patient is attached to the sensors and the device while they are falling asleep, it will be possible to watch the signals and observe the level of consciousness decrease. This will be a simulation of the application of the drugs used in an anesthesiology case. The effects of sleep will not be as strong as the effects of the drugs, but it should be possible to lower most of the signals at a level that will allow for a proper test.



Figure 59 are the electrodes that will be used in conjunction with the Biopac software.



Figure 58: Biopac electrodes

These electrodes are disposable foam Ag-AgCl snap electrodes. They are 38mm in diameter and have a 1cm contact area. These will be used for the ECG testing of the device. In order to connect the Biopac data acquisition software to the test subject we will need electrode leads.

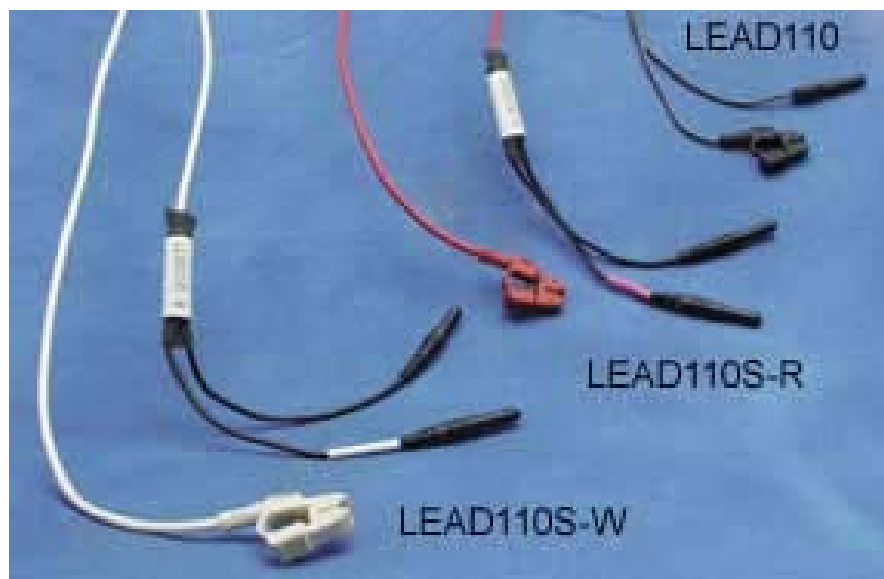


Figure 59: Biopac clip leads

These leads are designed for Biopac, and specifically for use with the disposable snap electrodes in Figure 59. The leads are shielded to prevent any interference, and are three meters long for an extended range of use.

Tests will also have to be run on the black fin once the LabVIEW™ program is installed on the chip. The chip will have to be able to support the memory to maintain the program when the chip is off. This will have to be able to function as a unit without a computer to compile and download the program onto it every time. This will have to be tested by making sure that a program can be loaded and maintained on the chip without compiling of the computer. A simple can be run and applied to make sure this is possible and to make sure that there are no problems with the LabVIEW™ data is applied and compiled onto the black fin.



2.2.2.13 Integration

The total monitor will have to integrate the LabVIEW™ program to the circuits and to the sensors. The sensors should input the data from the patient or test subject to circuit, where it will be amplified and filtered and then it will be sent to the LabVIEW™ program to clearly display the patient's current status through the use of graphs and numeric values. The circuit board will include all of the filtering and amplification. The advantages to using all electrical hardware for the signal manipulations once the circuit is build it is more robust and analog filtering and amplification provides better results. However the downfall to manipulating in the analog domain is that that all the filtering and amplification parameters are fixed, which eliminates any possibility of adjusting the parameters to optimize the displayed signal. The data is then converted to the digital domain where the signals are compiled into one DAQ assistant allowing the program to have one collaborative final output and will be able to analyze each signal simultaneously. The signal transducers will be implemented into circuit board where the data will be manipulated to reduce the noise. After the acquisition stage the input will then be ready for the LabVIEW™ program which will be installed onto a Blackfin® chip. Then the display screen will have to be attached to the circuit board to allow for a clear presentation of the signals. The Blackfin® chip is the ideal choice because it contains an internal analog to digital converter and it is much faster than traditional microcontrollers which have a speed around 20Mhz compared to the Blackfin®'s speed of around 350Mhz. Another reason why Blackfin® is the primary choice for this application is because Blackfin® has versatile programming code. The two codes that are compatible are C/C++ and LabVIEW™ VI's. The problem will be primarily consisting of LabVIEW™ code, but depending on the circumstances C++ may be used to obtain a certain result. The final program will then be implemented onto the Blackfin chip to control the function of the monitoring system.

2.2.2.14 Safety

The highest concern with these products is the chance for explosion. These monitors should not be used in a flammable atmosphere or where concentrations of flammable anesthetics may occur. They should also be kept away from MRI environments. These monitors are not designed to operate in temperatures outside of the range zero degree's C to 40 degree's C. Humidity should remain between 15% and 95%. Proper grounding is essential for the safety of the monitoring system. The BIS™ VISTA monitor may affect other equipment in the vicinity due to its electromagnetic interference. This means that the expert anesthesia monitoring system will have to be able to work in an EMI environment.

3 Realistic Constraints:

There are a number of organizations that specialize in developing and maintaining engineering standards for which projects must meet or exceed. Organizations such as the International Organization of Standardization (ISO), the International Electrotechnical Commission (IEC), and the Association for the Advancement of Medical Instrumentation (AAMI) are the ones responsible for these standards that all engineers must take into consideration when developing a device such as an expert anesthesiology monitoring device.



These standards are not only put in place for the patient's safety but also as guidelines for the engineering developers. They set a level of quality for each product which ultimately reduces the number of incompatible components when using a variety of different manufacturers; they also prevent unintentional misuse, and promote proper safety and effectiveness evaluations for each device. Before production medical devices are compared to three different groups of standards all of which must be met before production continues. The three groups are process standards, standard test methods, and performance standards.

Process standards provide a systematic way of accomplishing goals with a certain level of confidence. The most important process standard according to Kunst and Goldberg is the ISO 9001:2000 Quality Management Systems – Requirements which provides systematic methods for managing all aspects of manufacturing a device. This standard includes steps needed in purchasing raw materials, quality control, maintenance of manufacturing equipment, product servicing, and methods for training all users. For the expert anesthesiology monitoring system the design control section will provide the most applicable information because it deals with developing new devices. This section is relevant to product development because of the requirements it sets forth regarding establishing and documenting the product's design requirements, the evaluations of possible design hazards, final device specifications as well as establishing a correct method for transferring the design to the final large scale product.

Other relevant process standards are EN 1441:1997 Medical Devices – *Risk Analysis*, ISO 11135:1994 Medical Devices – *Validation and Routine Control of Ethylene Oxide Sterilization*, and BS 5295:1989 *Environmental Cleanliness in Enclosed Spaces*. EN 1441:1997 outlines the procedure that is preformed throughout the development process. It investigates the safety of the medical device by identifying hazards and estimating the risks associated with the hazards. ISO 11135:1994 provides development teams with procedures for validating their product's sterilization status and ensure the product will be sterile for field implementation. BS 5295:1989 sets regulation regarding the manufacturing environment to assure the final product will maintain a certain level of cleanliness suitable for medical applications.

Standard test methods are strict protocols for analyzing the physical properties or performance levels of the medical devices. Part of these standards only provide guidelines for testing allowing for comparisons based on complete and accurate data. Others provide specific test methods and criteria before the results will be considered acceptable. Two examples of Standard test methods are ISO 10993-1:1997 Biological Evaluation of Medical Devices – *Part 1: Evaluation and Testing* and ISO 10993-7:1995 Biological Evaluation of Medical Devices – *Part 7: Ethylene Oxide Sterilization Residuals*. ISO 10993-1:1997 specifies material safety tests and acceptance criteria which must be met before the device is considered to be biocompatible. ISO 10993-7:1995 lists special tests that the device must pass to assure the product does not contain toxic by-product during the sterilization.

Performance Standards accurately describe all performance attributes of the medical device. These protocols are unique for each device category, for example pacemakers, wheelchairs, vascular catheters, and medical aids such as the expert anesthesiology monitoring device. These standards commonly reference other previously created standards when



describing the qualities a device must possess which requires extensive background information. This way of intertwining the standards aids the development team with learning all of the standards relevant to their project.

A few examples of performance standards that are relevant to the expert anesthesiology are EN 980:1999 *Graphical Symbols for Use in the Labeling of Medical Devices*, EN 868-1:1997 *Packaging Material and Systems for Medical Devices Which are to be Sterilized – Part 1: General Requirements and Test Methods*, and EN 1041:1998 *Information Provided by the Manufacturer with Medical Devices*. EN 980:1999 provides a set of international symbols that eliminate the need for producing multilingual products. EN 868-1:1997 standardizes packaging to make it compatible with the sterilization process as well as storage. EN 1041:1998 requires the producers to provide a specific list of information which minimizes the risk and maximizes safety and effectiveness.

Economically the automated anesthesia monitoring system will require enough funding to purchase all of the probes and adapters for each vital sign. The amount of funding we receive will be proportional to the quality of devices. Top of the line devices will guarantee the minimum possible noise in the received signals; translating into a safer monitoring system due to more precise readings. Once system is complete, maintenance checks should occur on a regular basis to insure the functionality of each probe. Even if the probes are correctly functioning there an expiration date will limit their functioning duration to minimize failures during operation.

Configuring the monitor system for each patient requires a controlled environment to prevent any abnormal conditions that may alter the patient's normal vital signs. Any change in mental or physical state may jeopardize the patient's life. Minimizing the all stimuli is required for correct configuration of the system. Maintaining room temperature, eliminating any air contaminations, and ending any drug use prior to configuration are all possible factors that may influence the patient's vitals in such a way that will result in an incorrect configuration.

There are some serious ethical issues that must be considered to create a device that will be able to function in our society. The device must first off do no harm. This means that this device must not hinder the anesthesiologist's diagnosis of patient consciousness. Ethically this device may not be used unless it maintains a constant enhancement of performance of the anesthesiologist.

Politically the device has to be approved for use by the FDA's Quality System. This encompasses regulatory affairs, quality assurance, process development or manufacturing to maximize the performance of the mechanism. Before a medical device can be put on the market it must first meet all electrical safety requirements. The FDA 510(k) states that before introducing a device into the market, there must be a pre-market notification submitted, which allows the FDA to see if there is an equivalent device already on the market, to ensure effectiveness and safety. Ninety percent of all devices fail product certification testing the first time, due to rules that are unseen without total understanding of the testing process.

According to the FDA, there are three classes of medical devices. Class I devices are the least likely to cause harm to the user and require the least amount of regulatory control. Class II



devices require more control, including “special labeling requirements, mandatory performance standards and post-market surveillance”. Class III devices are those which are highly regulated and generally are important in sustaining human life, or present a “potential, unreasonable risk of illness or injury”. This device will most likely be a Class II device. The monitor will never directly cause harm to the patient, but if it malfunctions the patient could be harmed as a result of the malfunction, thus resulting in the Class II designation.

Socially we have to consider the patient’s reaction of placing their life in yet another automated system. As our society advances, we are relying on less human performance and more computer controlled devices. This is somewhat unsettling for the human psyche. Making sure that the device looks clean, simple and clear may help to settle the patients.

4. Safety Issues:

The safety of the patients as well as the hospital employees is a top priority. For the Expert anesthesiology monitoring device electrical, mechanical, thermal, biocompatibility and decontaminations are all important elements that need to be taken into consideration. If any element is overlooked the consequences could be devastating.

When formulating the electrical components great care must be taken to prevent electrical failure. Failure of these components can directly result in electrical fires and electrical injuries. Different failures can produce different types of injuries. Arc-Flash is a term used when heat and light energy emitted during an electrical fault. This arc-flash is caused by the break down of insulation between two energized components or these components and ground. Electrical contact refers to the nonfatal flow of electrical current through the near-by victim. The most serious result in electrical failure is electrocution which is an increased flow of electrical current through a human being that results in the death of the patient. The prevention and or resolution of electrical failures can occur only through full understanding and correct probing and analyses of the components under consideration.

Mechanical failure can also prove to be a serious problem for the monitoring device. The case enclosing the electrical circuit and interface screen could experience wear over time. This would increase the probability of failure if indeed the case no longer provides the protective enclosure it initially had. Other aspects of this system that could experience mechanical failure are the female and male adapters for each transducer. After a number of field trials these components may experience abnormal stresses. For example in-between surgical procedures the monitoring device may need to be repositions depending on the upcoming. During one of these repositions an accidental collision may occur. A step to increase the longevity of the system would be to include a replaceable barrier between the system and its external environment for additional protection.

Integrating thermal dissipation units will aid in preventing thermal failure and will be an essential factor in creating a successful device. Before selecting materials to aid in thermal dissipation the amount of thermal heat produced but the device should be estimated. This step will ensure the selected material is optimal. Selecting the correct material to withstand the



thermal dissipation is helpful when deciding between heat spreading devices and/or cooling systems to maintain a static environment within the monitoring device.

It is very important when designing an electrical device, especially one that is used in a surgical setting, to make sure that it is not subject to fire or explosion. Each year, in the United States alone, there are approximately 2,200 hospital fires, 20 to 30 of which occur in the operating room. Since the device will not have any fuel sources, the only concern will be an ignition source. Ignition sources include open flame, high heat, or electricity. This device can be fire-proofed by ensuring that there are no exposed live wires and no high heat sources in the device. All wires and electric components must be properly soldered and packaged. The device must not have any leakage current, which could also contribute to increasing the risk of fire.

Ensuring the monitoring device is biocompatibility with the patients is only applicable to the signal transducers because these elements will be the only components directly in contact with human tissue. To maximize the biocompatibility of these transducers the patient will have to list any allergies they may have. This safety issue is not a fatal problem but can create an uncomfortable environment for the patient before and after the surgery.

Decontamination of the monitoring device between patients will need to occur after each surgical procedure. This is applicable to all components that are in direct contact with the patient. After each procedure the signal transducers sterilized and the electrodes will need to be replaced. During manufacturing the device will need to be produced using a certain protocol to ensure the device is initially up to the engineering standards even before the device enters field applications.

5. Impact of Engineering Solutions

Our project is an automatic expert anesthesia monitoring system which will provide a surgeon or anesthesiologist with an accurate interpretation of a patient's level of consciousness. This monitoring system will positively impact the medical device market globally, economically, environmentally, and socially. The differences between our device and others on the market and the resulting impact will be substantial in the field of anesthesiology and anesthesiology monitoring. Our design is unique in that it uses three different vital signals instead of the typical single signal used by most current devices. While most devices on the market use just an electroencephalogram (EEG) signal, our design uses the addition of blood pressure, and an electrocardiogram (ECG). With the addition of these two additional signals this device provides a more accurate and dynamic interpretation of the patient's level of consciousness than previous devices. This will reduce the chance of error in the evaluation of a patient's level of consciousness, and in turn reduce the amount of accidents in the operating room as a result of a mistake on the behalf of the anesthesiologist. The device itself is intuitive, accurate, and cost efficient. It is small enough to be placed in an operating room unobtrusively, but large enough so it can be easily seen and used.

The global impact of this device will be seen in the changes to anesthesiology monitoring and the overall change in the involved tasks of an anesthesiologist. Medical devices are constantly being upgraded in order to reduce the amount of error, both human and mechanical,



that results from the use of such a device. The goal of this device is just that; to further reduce the mechanical and human error inherent in anesthesia monitoring. The basic purpose of a medical device is to make the job of whoever is using it easier by doing a portion of their work for them. Our monitoring system removes a good deal of the human element from consciousness monitoring by reducing the error of the device. The tasks that an anesthesiologist must perform are simplified as a result of the more accurate and easy to use monitor. The prospect of an easier to use and more accurate device will be extremely appealing to corporations, hospitals, patients, and especially doctors.

The environmental impact on the operating room will be minimal. Since the device will only be used in an operating room, and has relatively the same size and dimensions as current products, there will not be any change to the actual operating room environment as a result of the use of the new device. With the addition of the new signals, there are a number of new wires that need to be used, and could result in clutter that was not previously present. This could theoretically create a danger for doctors and nurses moving around an operating room. However, the device will be able to turn off certain inputs in order to customize the monitor for different types of surgeries. In an operating room, there are a number of alarms from a variety of different devices that can be heard throughout a surgery. It is important for the environment of an operating room that the alarms that will be used on this device are recognizably different from other alarms. They will also have to be at an appropriate volume so as not to overpower any other alarms present during surgery.

As with any electronic device, disposal of this device should be done through the proper channels. According to the Environmental Protection Agency (EPA), the disposal of electronic devices is an increasingly important task because of the harmful nature of many of the electronic components. The EPA has a Recycling Electronics and Asset Disposition (READ) program, which will find a contractor to dismantle an electronic device for proper disposal. In order to be appropriately disposed of, this device should go through this program.

The societal response toward this device could be one of mixed reactions. In general, with each new medical device that reaches the market, control is taken from the doctor and given to the new device. The prospect that a person's life is put in the hands of yet another automated machine could be discouraging to some people. At the same time, this could be a positive thing in the eyes of some people in that the element of human error will be removed. In general, most people will welcome a device that allows the operating room staff to focus more on the task at hand while the patient's safety is automatically maintained. The system of alarms will ensure that there will be no mechanical error, and once an alarm goes off the control will be put back in the hands of the anesthesiologist. Since most of the medical field is very conservative in what they consider a safe device, the effectiveness of this particular device will have to be proven.

The automatic anesthesia expert monitor will make the job of a surgeon or anesthesiologist much easier in the operating room. The device itself is basically an improvement on a current design, and uses a compilation of currently existing technologies. Ultimately, this device will be an accurate, easy to use, low cost anesthesia monitor that will play a large role in aiding an anesthesiologist.



6. Lifelong Learning

The design of this device requires a vast array of knowledge to build and program. Most of the technologies in the device, such as electric circuits and LabVIEW™ have been covered to a certain extent in our classes, but more was required of us. We needed to learn new software and concepts. This is where life long learning became important.

We needed to learn Microsoft Visio for schematic drawings early on in the design process. This program was crucial for writing reports since they involve the use of diagrams and figures. We needed to diagram circuits and physical designs of the device, and Visio was a program that could do both.

This design requires a level of understanding of the LabVIEW™ software that has not been taught in classes before this point. Our experience with LabVIEW™ has been spaced between several classes and has been fairly general. We were required to apply what we had already learned about the software while learning brand new techniques and ideas in order to create an original program that is specific to our device.

Our team needed to learn a great deal about electronic circuits for the project. We have had some background in electric circuits, but had never had any experience designing....By building the ECG device early on in the semester we learned the necessary soldering skills that we would need in creating the anesthesia monitor. We needed to learn how to check for leakage current in an electronic device to ensure that no current is emanating from the device through any of its external metal components or through the power cord. This was an important skill to learn since it could have devastating effects to either the patient or the operating room staff if it is not detected.

One very important thing that our team has learned is teamwork and time management. Very quickly we realized that is important to quickly and effectively delegate each person's role in the project. It is very important to have a sense of diplomacy in order to ensure the project is completed on time. Each team member must be able to communicate well with the rest of the team and do their share of the work. We have all had experience in teamwork before, but never to this extent. Time management was another extremely important lifelong learning experience. College itself is a lesson in time management, and this project furthers our knowledge in how to effectively manage our time.

In general, our team learned about research and design at a level that had previously not been experienced. This portion of the learning process is perhaps the most important. We must interact with our client at Hartford Hospital, and ensure that our design is appropriate for the client's needs. We needed to learn how to order parts and communicate with vendors, all while staying under budget.

This project as a whole requires learning new skills, and sharpening previously learned skills. From learning a new program to re-learning how to work as part of a team, this project has been a lifelong learning experience.



7 Budget and Timeline

7.1 Budget

The budget of this project is mostly indefinite and almost impossible to gauge. All the equipment that is necessary for this project would range in the half million dollar range. The BISTM monitor is worth upwards of two-hundred-thousand dollars alone. The GE-Marquette is worth near the same price. If the values of these two pieces of equipment are added together then there is upwards of four-hundred-thousand dollars being spent on just the preliminary equipment.

Considering the amount of money that would be required to purchase a touch screen monitor which was removed from the project due mainly to cost. For this project to be 100 percent perfect for a surgery it would best be done with touch screen.

Also if this were to be done with out any prior equipment supplied there would be costs of National Instruments equipment. This would range in the tens of thousands of dollars. This would include the software which goes for a couple thousand dollars. This is all already purchased by the University of Connecticut and as such there is reasonable access to it.

Blackfin is another huge purchase that is being supplied through the University of Connecticut. Using their Blackfin[®] it will be possible to transfer the information onto the chip and run it through. This will hopefully help to reduce the equipment size.

The economic impact of this device can affect consumers of the product, both doctors and hospitals, and the patients as well. At this point in time, the budget has been estimated to be between \$590 and \$2155. Aside from the device itself, the only equipment the hospital is required to have for full use of the device is the electrode/lead sets for the three signals. This is a relatively low overall cost to pay for a device that has such a high benefit. Every operating room has an anesthesia monitoring/delivery system, and generally all hospitals try to update their equipment as much as possible in the interest of the safety of the patients. For this reason, with the introduction of this new and improved device, the demand for informational support for the anesthesiologist are becoming viably necessary.



Part	Cost	Shipping and Handling
EEG Flex/Pro Sensor	\$250	\$39.99
Power Source – Double-Fused Three Function Power Entry Module	\$31.34	Unknown
Power Source cord	\$4.96	Unknown
UFO Cube Computer Case	\$299.99	Unknown
LCD6VGA 8” Open Frame TFT	\$599.99	\$49.99
ADI Blackfin [®] Processor	\$23.63	Unknown
Ultra Copper Core Cooling Fan	\$14.13	Unknown
(ON)-OFF SPST Momentary	\$2.50	\$1
RS422 Serial Cables	\$7.50	\$1.75
Resistor- 226-1058-ND	\$5 each	Unknown
Capacitor -338-1364-ND	\$3 each	Unknown
Op-Amplifiers- 296010025-2-ND	\$5.10 each	Unknown

Table X: Budget outline



7.2 Timeline:

	i	Task Name	Duration	Start	Finish
1		Machine shop certification (TJ)	4 days	Mon 5/14/07	Thu 5/17/07
2		Machine shop certification (Nate)	4 days	Mon 5/14/07	Thu 5/17/07
3		Machine shop certification (Kane)	4 days	Mon 5/14/07	Thu 5/17/07
4		Obtain BisVista and GE monitors from Hartford Hospital	1 day?	Wed 5/16/07	Wed 5/16/07
5		Learn LabVIEW program	2 days	Wed 6/13/07	Thu 6/14/07
6		Meet with NI rep (Newton Defaria)	1 day?	Wed 8/29/07	Wed 8/29/07
7		Parts order	1 day?	Fri 4/27/07	Fri 4/27/07
8		LabVIEW - determine filter locations and functions	1 day?	Wed 4/25/07	Wed 4/25/07
9		LabVIEW - Create equations to determine patient consciousness level	1 day?	Tue 4/24/07	Tue 4/24/07
10		LabVIEW - Incorporate equations into program to alter drug administration	1 day?	Wed 10/10/07	Wed 10/10/07
11		LabVIEW - Create LabVIEW schematic for LCD display	1 day?	Thu 9/13/07	Thu 9/13/07
12		LabVIEW - Create LabVIEW schematic for Button controls	1 day?	Thu 9/27/07	Thu 9/27/07
13		LabVIEW - Create LabVIEW schematic to interpret GE and BisVista monitors	1 day?	Mon 10/8/07	Mon 10/8/07
14		LabVIEW - Create LabVIEW schematic to combine signals	1 day?	Mon 10/8/07	Mon 10/8/07
15		LabVIEW - Create LabVIEW schematic to combine patient data with monitor data	1 day?	Tue 10/9/07	Tue 10/9/07
16		LabVIEW - ensure program works for monitor output and button control	1 day?	Wed 10/17/07	Wed 10/17/07
17		Test LabVIEW program with Joseph McIsaac	1 day?	Wed 11/28/07	Wed 11/28/07
18		Send updates to client periodically to stay on the correct track	1 day?	Wed 9/19/07	Wed 9/19/07
19		Put LabVIEW program onto Blackfin processor	1 day?	Wed 11/21/07	Wed 11/21/07
20		Configure LCD screen so it properly displays the patient's data	1 day?	Tue 10/16/07	Tue 10/16/07
21		Configure Blackfin processor to run LabVIEW with the appropriate parameters	1 day?	Wed 10/24/07	Wed 10/24/07
22		Configure Blackfin and LabVIEW to display on LCD screen	1 day?	Thu 11/29/07	Thu 11/29/07
23		Configure Blackfin to interface with buttons/human interaction	1 day?	Tue 11/27/07	Tue 11/27/07
24		Test Blackin with EZ-lite	1 day?	Tue 10/23/07	Tue 10/23/07
25		Design and order appropriately sized case	1 day?	Thu 9/6/07	Thu 9/6/07
26		Determine appropriate LCD screen size	1 day?	Tue 8/28/07	Tue 8/28/07
27		Attach LCD screen to the output of the Blackfin circuit to ensure proper function	1 day?	Wed 10/31/07	Wed 10/31/07
28		Configure Blackfin to output signal to drug delivery device	1 day?	Thu 11/29/07	Thu 11/29/07
29		Perform human tests with Biopac software	1 day?	Tue 10/16/07	Tue 10/16/07
30		Test alarms using a function generator	1 day?	Wed 11/28/07	Wed 11/28/07
31		Determine proper location of all components within case	1 day?	Mon 10/29/07	Mon 10/29/07
32		Machine case to fit LCD screen	1 day?	Thu 10/25/07	Thu 10/25/07
33		Machine case to fit buttons	1 day?	Thu 10/25/07	Thu 10/25/07
34		Machine case to fit power supply	1 day?	Thu 10/25/07	Thu 10/25/07
35		Machine ventilation slots in rear of case	1 day?	Thu 10/25/07	Thu 10/25/07
36		Machine case to fit fan	1 day?	Thu 10/25/07	Thu 10/25/07
37		Mount LCD screen in case	1 day?	Fri 10/26/07	Fri 10/26/07
38		Attach power supply to case	1 day?	Fri 10/26/07	Fri 10/26/07
39		Mount fan in case	1 day?	Fri 10/26/07	Fri 10/26/07
40		Mount buttons on front panel of the case	1 day?	Mon 10/29/07	Mon 10/29/07
41		Connect LCD to blackfin chip and ensure proper function	1 day?	Wed 10/31/07	Wed 10/31/07



	i	Task Name	Duration	Start	Finish
42		Connect Buttons to blackfin chip and ensure proper function	1 day?	Tue 10/30/07	Tue 10/30/07
43		Update Website	1 day?	Fri 8/31/07	Fri 8/31/07
44		Update Website	1 day?	Fri 9/7/07	Fri 9/7/07
45		Update Website	1 day?	Fri 9/14/07	Fri 9/14/07
46		Update Website	1 day?	Fri 9/21/07	Fri 9/21/07
47		Update Website	1 day?	Fri 9/28/07	Fri 9/28/07
48		Update Website	1 day?	Fri 10/5/07	Fri 10/5/07
49		Update Website	1 day?	Fri 10/12/07	Fri 10/12/07
50		Update Website	1 day?	Fri 10/19/07	Fri 10/19/07
51		Update Website	1 day?	Fri 10/26/07	Fri 10/26/07
52		Update Website	1 day?	Fri 11/2/07	Fri 11/2/07
53		Update Website	1 day?	Fri 11/9/07	Fri 11/9/07
54		Update Website	1 day?	Fri 11/16/07	Fri 11/16/07
55		Update Website	1 day?	Fri 11/23/07	Fri 11/23/07
56		Update Website	1 day?	Fri 11/30/07	Fri 11/30/07
57		Update Website	1 day?	Fri 12/7/07	Fri 12/7/07
58		Weekly Report	1 day?	Fri 8/31/07	Fri 8/31/07
59		Weekly Report	1 day?	Fri 9/7/07	Fri 9/7/07
60		Weekly Report	1 day?	Fri 9/14/07	Fri 9/14/07
61		Weekly Report	1 day?	Fri 9/21/07	Fri 9/21/07
62		Weekly Report	1 day?	Fri 9/28/07	Fri 9/28/07
63		Weekly Report	1 day?	Fri 10/5/07	Fri 10/5/07
64		Weekly Report	1 day?	Fri 10/12/07	Fri 10/12/07
65		Weekly Report	1 day?	Fri 10/19/07	Fri 10/19/07
66		Weekly Report	1 day?	Fri 10/26/07	Fri 10/26/07
67		Weekly Report	1 day?	Fri 11/2/07	Fri 11/2/07
68		Weekly Report	1 day?	Fri 11/9/07	Fri 11/9/07
69		Weekly Report	1 day?	Fri 11/16/07	Fri 11/16/07
70		Weekly Report	1 day?	Fri 11/23/07	Fri 11/23/07
71		Weekly Report	1 day?	Fri 11/30/07	Fri 11/30/07
72		Weekly Report	1 day?	Fri 12/7/07	Fri 12/7/07
73		Weekly meeting	1 day?	Fri 8/31/07	Fri 8/31/07
74		Weekly meeting	1 day?	Fri 9/7/07	Fri 9/7/07
75		Weekly meeting	1 day?	Fri 9/14/07	Fri 9/14/07
76		Weekly meeting	1 day?	Fri 9/21/07	Fri 9/21/07
77		Weekly meeting	1 day?	Fri 9/28/07	Fri 9/28/07
78		Weekly meeting	1 day?	Fri 10/5/07	Fri 10/5/07
79		Weekly meeting	1 day?	Fri 10/12/07	Fri 10/12/07
80		Weekly meeting	1 day?	Fri 10/19/07	Fri 10/19/07
81		Weekly meeting	1 day?	Fri 10/26/07	Fri 10/26/07
82		Weekly meeting	1 day?	Fri 11/2/07	Fri 11/2/07



	i	Task Name	Duration	Start	Finish
83		Weekly meeting	1 day?	Fri 11/9/07	Fri 11/9/07
84		Weekly meeting	1 day?	Fri 11/16/07	Fri 11/16/07
85		Weekly meeting	1 day?	Fri 11/23/07	Fri 11/23/07
86		Weekly meeting	1 day?	Fri 11/30/07	Fri 11/30/07
87		Weekly meeting	1 day?	Fri 12/7/07	Fri 12/7/07
88		Make sure no electrical components are touching in case	1 day?	Thu 11/22/07	Thu 11/22/07
89		Perform leakage current tests and fix if necessary	1 day?	Tue 11/27/07	Tue 11/27/07
90		Debug Blackfin/LCD interface	1 day?	Tue 11/27/07	Tue 11/27/07
91		Debug Blackfin/LabVIEW interface	1 day?	Tue 11/27/07	Tue 11/27/07
92		Debug Blackfin/button interface	1 day?	Tue 11/27/07	Tue 11/27/07
93		Write operator's manual	1 day?	Thu 11/29/07	Thu 11/29/07
94		Write final report	1 day?	Mon 12/3/07	Mon 12/3/07
95		Give device to the client	1 day?	Thu 12/6/07	Thu 12/6/07
96		Create powerpoint presentation	1 day?	Wed 12/5/07	Wed 12/5/07
97		Prepare for senior design day	1 day?	Tue 11/6/07	Tue 11/6/07
98		Finishing Touches	1 day?	Thu 12/6/07	Thu 12/6/07
99		Device demonstration	1 day?	Fri 12/7/07	Fri 12/7/07
100		Presentation	1 day?	Fri 12/7/07	Fri 12/7/07

Table X: Timeline

8 Team Members Contribution to the Project

During the semester, Team #2 has met multiple times during each week to work on the design together. For the most part this project was designed and planned by all the members in the group. The work which was completed by each individual is summarized below.

Timothy Morin was one of the main writers of the group. He researched the Aspect BIS monitor system and contacted Eleanor Halgren who helped to find the capabilities of the BIS system and how it would be used. He did most of the research based on the patents and the original system design. He took the leader position for most of the first semester of the project. Timothy did a great deal of research on the patient's prior information and how it would be related to the diagnostic dosages of anesthesia. The patient's prior information has been manipulated and the calculations for how to obtain dosage changes was done and applied to LabVIEW™ by Timothy. He also did the research and discussion on the connectors and how they would function and plug into and transfer the data from one device to the other. He found the information on how LabVIEW™ was going to be tested and how the total testing would be done. The integration of all the products into LabVIEW™ was researched and worked on by Timothy. The safety issues that had to be addressed were also done by Timothy.

Kane focused most of his research on the physical components of the device. He contacted various vendors about the parts required in an attempt to choose the appropriate components. Once he decided on the components that will go into the device, he drew Visio drawings of the case and buttons. Kane did research into the buttons for the outside of the device to see how they work. After learning about their operation he picked the best design for the buttons that would be used, and designed the layout of the front side of the case. He also researched into a power source for the device, and determined the best components required to power it. For each of the alternative designs Kane edited and formatted the reports, and checked



each one for continuity. In the final design report, he set up the timeline for the remainder of the design process. In general, he has taken charge of the physical device itself and the selection and installation of the components of the device.

Nathan headed the research involving the GE-Marquette device, electrical filtering, Blackfin[®] Processor, real time processing, and digital signal processing. He also obtained contact within National Instruments. Currently he is working with Michael Wasson, the NI rep, to identify the method to create the LabVIEW[™] program. We set tentative to meet over the summer break, which will provide the necessary guidance to successfully implement our LabVIEW[™] program and integrate it onto the Blackfin[®] microprocessor. To understand how to incorporate the data received from the GE-Marquette device, Nathan used the user manual to unravel how exactly the output data will be formatted and what the data needs to successfully obtain the packaged data. With this knowledge the group gained a greater understanding of what the LabVIEW[™] program for the GE-Marquette will need to successfully parse the data packets. Nathan researched real time processing and digital signal processing because Dr. McIsaac explained that our device needed to process in the real-time as well as having accurate results. Understanding what digital signal processing is will allow the group to optimize their code and their hardware minimizing processing time and the error.

9 Conclusions:

As time advances, so does the technology that is helping to support life in the operating room and outside of it. The monitoring of patients health is becoming increasingly more prevalent in the hospital setting. The expert anesthesia monitoring system is going to be able to use the GE-Marquette anesthesia monitor and the aspect medical BIS[™] EEG monitor to support the life of a patient in the operating room. This technology is class three and if something malfunctions then there could be serious implications. This will be one of the first technologies that will actually incorporate patient information and levels of consciousness to diagnose a proper dosage of anesthetic to continue a patient under anesthesia. There is a need for devices that will be able to back up the knowledge of the anesthesiologist in the surgical setting. With this device there will be a way to recall and support all of the anesthesiologist's dosages and processes in surgery.

The basic design of this project has been engineered by understanding of the client and the advisors needs. These design constraints were unclear at first but now seems to have a clear direction. This project started off as an anesthesia monitor that would judge the level of consciousness of a patient based primarily on the obtaining of vital signals from patients. This has evolved into an expert anesthesiology monitoring system that imports signals from the GE-Marquette anesthesia monitor and the aspect medical BIS[™] EEG monitor and calculates from that a new level of consciousness. This new value will then be evolved even further using the patient's prior information to give even more accuracy. Then this value will be used to determine a set dosage that is necessary to be applied to the patient to keep them at the correct level of anesthetic.



To construct a medical care device that is reliable, safe, and will meet the FDA regulations and strict guidelines of the United States, there must be no chance for a patient to have overtly bad side affects. This design will is being designed to be as safe and accurate as possible. The most stringent of policies have to be applied when considering a device that will help to support human life. The two signals that will be used from the GE-Marquette anesthesia monitor and the aspect medical BISTM EEG monitor will be passed through two transducers that will be able to obtain the data from the monitors and input them into the Blackfin[®] chip that will be in the expert anesthesia monitoring system. These transducers will have to pass the signals with little to no loss of data and very little gain of noise. This noise will have to then be removed from the signal, preferably without affecting the actual data acquisitioned. The LCD monitor will then have to be attached to the Blackfin[®] as well. This will be very important to allow for a clear and failsafe image of information and output data. The last component of the device will be a number key pad that will have to be able to allow for the numerical values of the patient to be inserted into it with little to no effort in understanding by the doctor. Then there will be a down arrow which will be depressed and allow for the doctor to sort through the patient's information and alter it at any point. This simple method for data insertion allows for safety and very little room for error on the doctors part. This is important because at a time of life or death, the doctor has to be able to change information quickly without a chance for misunderstanding. This is going to be the safest way and more reliable way to input the information.



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11 Acknowledgements

John Enderle
William Pruehsner
Monty Escabi
Joseph McIsaac
Anastasios Maurudis
David Kaputa



12 Appendix

12.1 Updated Specifications

Electrical Parameters

Power Source	120V A/C or rechargeable batteries if wireless
Display	LABVIEW Front Panel
Height	8" max
Width	10" max
Illumination	Visible in bright fluorescent lights
Range	50' (if wireless)
Software:	LABVIEW
ECG Specifications	
BPM	60-100 bpm with 13Hz
PR interval	0.12 to 0.20s
QT interval	0.42s
EEG Specifications	
Band pass filter	
Lower Cutoff frequency:	0.5Hz
Upper Cutoff frequency:	500Hz
Alpha wave	8-13Hz
Beta waves	>13Hz
Theta waves	3.5-7.5Hz
Delta waves	3Hz or less
Tidal Volume	500ml
Respiratory rate	14 breaths per minute

Mechanical Parameters

Button Size	1" x 1" max
Actuation Pressure	Responsive enough for easy operation, but resistant to unintended activation
Size	No larger than current systems: ≈ 12" x 10" x 5"
Weight	>10lbs
Durability	Maintain nominal operation in a surgical setting

Environmental Parameters

Location	Operation Room
Dust	Negligible
Operating Temperature	30°-100°F
Storage Temperature	0°-110°F

Housekeeping	Programmable EEG, ECG, and TV alarms
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12.2 Purchase Requisitions and FAX quotes

PURCHASE ORDER REQUISITION - UCONN BME SENIOR DESIGN LAB

Instructions: Students are to fill out boxed areas with white background

Each Vendor will require a different purchase requisition

Date:	April 20, 2007	Team #	2	Total Expenses	N/A
Student Name:	Nathan White				
Ship to:	University of Connecticut Biomedical Engineering U-2247, 260 Glenbrook Road Storrs, CT 06269-2247	Lab Admin only:			
Attn:		FRS #		Student Initial Budget	
Project Name:	Expert Anesthesiology Monitoring device	Student Current Budget		Project Sponsor	
ONLY ONE COMPANY PER REQUISITION					
Catalog #	Description	Unit	QTY	Unit Price	Amount
LM404	LM-404R Quad 4-Inch LCD Monitor BNC and S-video Inputs	###	1	\$1,199.95	\$1,199.95
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
					\$0.00
Comments					
Price Quote				Shipping	\$16.10
File Name:				Total:	\$1,199.95
Yes or No	Vendor Accepts Purchase Orders?				
Vendor:	B&H Photo-Video-pro audio				
Address:	http://www.bhphotovideo.com				
Phone:	800.336.7408 / 212.502.6234				
Contact Name:	N/A				
Authorization:					